



Mallinckrodt Inc.

August 24, 2009

Materials Licensing Section
U.S. Nuclear Regulatory Commission
2443 Warrenville Road, Ste. 210
Lisle, IL 60532-4352
Attention: Mr. Kevin Null

RE: License Number 24-04206-01; Docket Number 030-00001

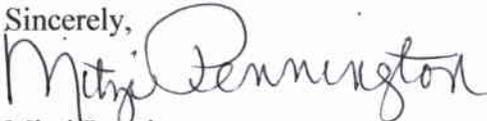
Dear Mr. Null:

Enclosed herewith is an application for amendment to the above referenced license. The changes, which are incorporated in the enclosed application for amendment, include updated site information and changes that have been made, in accordance with our license, with regard to the radiation protection program.

The attached list of changes was developed in order to facilitate your review of the application. The changes for Sections 5 and 6 reflect changes from the most recent (June 22, 2009) application for amendment. The changes for Sections 7 through 11 reflect changes from the February 2001 application for renewal.

For clarification purposes, the enclosed amendment request is in addition to the pending amendment request dated June 22, 2009.

If you have any questions regarding this letter or the enclosures, please contact me, Dan Hoffman at 314-654-7906 or Jim Schuh at 314-654-7981.

Sincerely,

Mitzi Pennington
Site Director

cc: Jim Schuh – Mallinckrodt
Dan Hoffman -- Mallinckrodt

RECEIVED AUG 25 2009

Mallinckrodt Inc.
List of Changes in the Current
Application for Amendment to License No. 24-04206-01

Changes are identified by section number. If the section number does not appear below, there were no changes required for that section.

Section 5, Radioactive Materials to be Possessed:

1. Pages 4-5: Deleted the phrase “curies per nuclide” in the third column of Table 5-1 after the maximum possession limits for Cu-64, Ga-66 and In-110.
2. Page 5: Changed the entry in the second column of Table 5-1 for item “o” from “Metal (in slab form for calibrations)” to “Metal (in slab form)”.
3. Page 5: The second sentence in the note below Table 5-1 was deleted.

Section 6, Purpose for which Licensed Materials will be Used:

1. Page 6: In the second paragraph, clarification was provided regarding materials that may be accepted from Mallinckrodt customers and pharmacies. This incorporates the information included in our letter to NRC dated December 8, 2005.

Section 7, Individuals Responsible for the Radiation Safety Program:

1. Page 7: Under the “Radiation Safety Committee” section, the list of positions represented on the committee were updated.
2. Pages 8 and 9: Figures 7.1 and 7.2 were updated to reflect the current organizational and reporting structure.
3. Page 11: In the sentence beginning with “Prior to implementation”, the term “license renewal application” was changed to “application for license amendment”.
4. Page 14: The last two paragraphs on the page regarding delegation of RSO authority were reworked and combined into a single paragraph.

Section 8, Training for Individuals Working in or Frequenting Restricted Areas:

1. Page 20: The paragraph under “Visitors” was changed to incorporate the current process for authorizing visitors to enter the site as a logbook is no longer necessary with the electronic security system. Further it is stated that anyone entering site shall be informed that radioactive materials are used at the site.
2. Page 20: Added a note at the end of the “Class IV Level of Training” section clarifying that Class IV employees may enter radiological restricted areas under direct supervision of a qualified individual only if they are provided with additional specialized augmentee training.
3. Page 21: The first paragraph under “Class I Level of Training” was modified to incorporate the change described in Mallinckrodt’s letter of August 16, 2004.

Section 9, Facilities and Equipment:

1. On page 19 of the renewal application for License 04-04206-01 dated February 2001 reference was made to a Section 9.3 in the last sentence of the introductory

paragraph in Section 9. However, none of the sections were identified as Section 9.3 in the application. To correct this, the section titled "Sealed Source Storage Locations" has been changed to "Sealed Sources" and numbered as Section 9.3 (see page 41 of the current amendment request).

2. Page 23: In the second to last sentence of the first paragraph of Section 9, the word "Finally," was removed.
3. A new sentence has been added at the introductory paragraph for Section 9 that reads as follows:
"Section 9.4 describes the change control process that is used for changes to facilities and/or equipment, including RSO and RSC reviews."

Section 9.1, Description of Site and Buildings:

1. Page 23: The first two paragraphs in Section 9.1 were revised to clarify that access to the main site and to Building 150, including the Building 150 vehicle gate, are now controlled with the use of an electronic card reader system.
2. Page 24: An updated site plan was included as Figure 9-1.
3. Page 25: Table 9-1 was updated to include Building 250A.
4. Page 26: The section previously titled "Building 250" was changed to "Building 250/250A". The section was also changed to clarify that a new Building 250A was added to contain lower contact dose rates. It was also changed to clarify that wastes may be stored in these buildings for a period of several months or longer before being shipped offsite for disposal.
5. Page 27: The section titled "Building 600" was revised to incorporate activities and facilities where cyclotron produced radionuclides are received and processed. Also makes reference to a new Figure 9.5 that shows the layout of the R/A Processing, R/A Dispensing and R/A Packaging Labs.
6. Page 28: The location of Table 9-2 was changed. It now appears before Figures 9-2 through 9-7.
7. Page 28: Table 9-2 was updated. I-125 was removed as this nuclide is not currently being processed at the Maryland Heights plant. Table 9-2 was also updated to reflect the current possession limit for Xe-133; processing frequencies were deleted altogether; and various location changes were made for processing, dispensing, storage and packaging of Cr-51, I-123 and In-111.
8. Page 28: The last two sentences from the section titled "Buildings 700 and 800", which were related to regulation of the cyclotron produced radioactive materials by the State of Missouri, were deleted.
9. Page 28: Added a paragraph to reference Table 9-3, General Information on Maryland Heights Cyclotrons. Created a new Table 9-3 that provides information regarding the six cyclotron units at the Maryland Heights plant. Added a paragraph after Table 9-3 that references the floor plans for Buildings 700 and 800. Also includes reference to the location of the two primary labs where processing of cyclotron targets occurs.
10. Pages 29-34: Added updated drawings of the site and added new drawings for the buildings that house the cyclotrons.
11. Page 36: The last sentence in the third paragraph was revised to read as follows:

- “If there are any changes from the predetermined set points, an alarm is activated at the local panel, the guard station, and/or at the Health Physics alarm monitor.”
12. The table that was titled “Stack and Building Data” on page 30 of the February 2001 application was deleted as it is not considered relevant or applicable to the application. Subsequent tables in Section 9 were renumbered.
 13. Pages 37-38: The table titled “Radioactive Exhaust System and Radionuclide Release Information” (Table 9-4) was updated based on ventilation system modifications that were completed after the February 2001 application was submitted. In addition, a statement was added to the end of Table 9-4 to clarify what is meant by the information under the “Filter Arrangement” column.

Section 9.2, Description of Special Application Facilities:

1. Page 38: Section 9.2, the term “hotcell” was changed to “hot cell”. This change was also made in other parts of the document where this term appears.
2. Page 39: A new section titled “Miscellaneous Radioactive Materials Processing” was added after the section titled “Mo/Tc-99m Hot Cell”. The new section provides a description of the equipment and locations where Ga-67, In-111 and Tl-201 products are processed.
3. Page 40: In the first full paragraph, changes were made to include a discussion about the use of Building 250A.
4. Page 41: In Table 9-5, “Areas Currently Housing Processes Involving > 100 mCi”, entries were made describing areas in Buildings 700 and 800 where large quantities of radioactive material are processed.

Section 9.3, Sealed Sources:

1. Page 41: In the application dated February 2001 there was a reference to a Section 9.3 in the last sentence that addressed sealed sources in the first paragraph of Section 9; none of the sections were identified as Section 9.3. To correct this, the section titled “Sealed Source Storage Locations” has been changed to “Sealed Sources” and numbered as Section 9.3.
2. Page 41: The first paragraph of Section 9.3 was revised to remove text related to TLD irradiations and on-site TLD processing.
3. Pages 41-43: Table 9-6, “Sealed Sources and Storage Locations” was updated to add 6 new sources that were not listed on the February 2001 application. Various changes were also made with respect to the storage locations for some of the sources. In addition, the table was updated to clarify that none of the sources are used for TLD irradiations.

Section 9.4:

1. Page 43: The section titled “Proposed Changes to Facilities and Equipment” was numbered as section 9.4. No changes were made to the text in that section.

Section 10.1, Audit Program:

1. Page 44: A sentence was added to the end of the first paragraph that reads as follows: “The latter two types of audits maybe combined into a single audit.”

2. Page 46: The paragraph relating to Radiation Safety Committee review of all audits reports and responses was deleted.

Section 10.2, Radiation Monitoring Instruments:

1. The last two sentences in the last paragraph under the section titled “Portable Radiation and Contamination Level Measuring Instruments” was deleted.
2. Page 48: The section titled “Portal Monitors” was revised to incorporate the addition of new Canberra portal monitors.
3. Page 48: The section titled “Stationary Counting Equipment” has been revised in its entirety. Current methods and frequencies for calibration of the stationary counting systems are based on site experience and manufacturer recommendations.
4. Page 49: The section titled “Specific Program Elements for Portable Radiological Instrument Calibrations” was changed to “Portable Radiological Instrument Calibrations”. The first paragraph in this section was revised to clarify that the Health Physics Department is responsible for calibration of portable instruments.
5. Page 49: The section titled “Radiation level survey instruments are calibrated as follows:” was revised to read “Calibration of Radiation Level Survey Instruments”.
6. Page 50: An additional item 8 has been added to the end of the new section titled “Calibration and Source Checks for Radiation Level Survey Instruments”. Item 8 describes the requirement for the daily source checks for each day the instruments are used.
7. Page 50: The section titled “Contamination Survey Level instruments (full calibration) are calibrated as follows;” was revised to read “Calibration of Contamination Level Survey Instruments”.
8. Page 51: The sections titled “Contamination Level Survey instruments (full calibration) are calibrated as follows:” and “Contamination Level Survey instruments (source response only) are calibrated as follows:” was revised to read “Source Checks for Count Rate Instruments”. This section was simplified by deleting unnecessary levels of detail that is provided in approved written procedures.
9. Page 52: The first paragraph was revised to clarify that the Health Physics Department is responsible for records maintenance.
10. Page 52: The section titled “Portal Monitors” was revised to clarify that the Health Physics Department is responsible for records maintenance.

Section 10.3, Material Receipt and Accountability:

1. Pages 53-54: The paragraph under the section “Inventory of Radioactive Materials” was revised to clarify that entry of radioactive material information into the site inventory management program may occur upon receipt or production, depending on whether the materials are produced onsite or received from outside vendors.
2. Page 54: In the table shown under the section titled “Records of RAM Receipt, Transfer and Disposal”, the retention duration was changed from 3 years to 5 years for received and transferred radioactive material.

Section 10.4, Occupational Dose:

1. Page 54: In the second paragraph of this section the term “TLD badge” was changed to “dosimeter badge” and the last sentence was deleted.
2. Page 55: In the first paragraph, reference to direct reading dosimeters (DRDs) was removed.
3. Page 55: In the second paragraph the last sentence was deleted.

Section 10.6, Safe Use of Radionuclides and Emergency Procedures:

1. Page 56: In the ninth bullet item, “direct reading dosimeters” was replaced with “electronic personal dosimeters”.

Section 11, Waste Management:

1. Page 63: The last two sentences of the second paragraph have been revised to clarify which wastes may be accepted at the Maryland Heights site and the instructions that will be provided to customers and Mallinckrodt pharmacies regarding the return of radioactive material to the site.

APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS
 DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
 U.S. NUCLEAR REGULATORY COMMISSION
 WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
 DIVISION OF NUCLEAR MATERIALS SAFETY
 U.S. NUCLEAR REGULATORY COMMISSION, REGION I
 475 ALLENDALE ROAD
 KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
 U.S. NUCLEAR REGULATORY COMMISSION, REGION III
 2443 WARRENVILLE ROAD, SUITE 210
 LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
 U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
 612 E. LAMAR BOULEVARD, SUITE 400
 ARLINGTON, TX 76011-4125

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

A. NEW LICENSE

B. AMENDMENT TO LICENSE NUMBER 24-04206-01

C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Mallinckrodt Inc.
2703 Wagner Place
Maryland Heights, MO 63043

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Mallinckrodt Inc.
2703 Wagner Place
Maryland Heights, MO 63043

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Daniel E. Hoffman

TELEPHONE NUMBER

(314) 654-7906

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
 a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

9. FACILITIES AND EQUIPMENT.

11. WASTE MANAGEMENT.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

10. RADIATION SAFETY PROGRAM.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY **3A** AMOUNT ENCLOSED **\$ 0.00**

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Mitzi Pennington, Site Director

SIGNATURE

Mitzi Pennington

DATE

24 Aug 09

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

Section 5

Table 5-1 Radioactive Materials to be Possessed

Radionuclide	Chemical/ Physical Form	Maximum Possession Limit	Proposed Use
a. Any byproduct material with Atomic Numbers 1 through 83 (except as specified below):	Any	Not to exceed 100 curies per radionuclide, total possession limit 300 curies (except as specified below):	Production and possession of a radiochemical for research and development of radiopharmaceuticals. For use in manufacturing, processing and packaging of radiopharmaceuticals and/or radiochemicals. For possession and storage incident to production activities.
b. Mo-99	Any	13,000 curies	Production and possession of a radiochemical for research and development of radiopharmaceuticals. For use in manufacturing, processing and packaging of radiopharmaceuticals and/or radiochemicals. For possession and storage incident to production activities.
c. Tc-99m	Any	10,000 curies	Production and possession of a radiochemical for research and development of radiopharmaceuticals. For use in manufacturing, processing and

Section 5

Radionuclide	Chemical/ Physical Form	Maximum Possession Limit	Proposed Use
			packaging of radiopharmaceuticals and/or radiochemicals. For possession and storage incident to production activities.
d. I-131	Any	500 curies	Production and possession of a radiochemical for research and development of radiopharmaceuticals. For use in manufacturing, processing and packaging of radiopharmaceuticals and/or radiochemicals. For possession and storage incident to production activities.
e. Xe-133	Any	800 curies	Production and possession of a radiochemical for research and development of radiopharmaceuticals. For use in manufacturing, processing and packaging of radiopharmaceuticals and/or radiochemicals. For possession and storage incident to production activities.
f. Ga-67	Any	300 curies	Production and possession of a radiochemical for research and

Section 5

Radionuclide	Chemical/ Physical Form	Maximum Possession Limit	Proposed Use
			development of radiopharmaceuticals. For use in manufacturing, processing and packaging of radiopharmaceuticals and/or radiochemicals. For possession and storage incident to production.
g. In-111	Any	30 curies	Production and possession of a radiochemical for research and development of radiopharmaceuticals. For use in manufacturing, processing and packaging of radiopharmaceuticals and/or radiochemicals. For possession and storage incident to production activities.
h. Pb-201	Any	1050 curies	Production and possession of a radiochemical for research and development of radiopharmaceuticals. For use in manufacturing, processing and packaging of radiopharmaceuticals and/or radiochemicals. For possession and storage incident to production activities.

Section 5

Radionuclide	Chemical/ Physical Form	Maximum Possession Limit	Proposed Use
i. TI-201	Any	350 curies	Production and possession of a radiochemical for research and development of radiopharmaceuticals. For use in manufacturing, processing and packaging of radiopharmaceuticals and/or radiochemicals. For possession and storage incident to production activities.
j. I-123	Any	10 curies	Production and possession of a radiochemical for research and development of radiopharmaceuticals. For use in manufacturing, processing and packaging of radiopharmaceuticals and/or radiochemicals. For possession and storage incident to production activities.
k. Cu-64	Any	3500 curies	Possession and storage incident to production activities.
l. Ga-66	Any	800 curies	Possession and storage incident to production activities.
m. In-110	Any	200 curies	Possession and storage incident to

Section 5

Radionuclide	Chemical/ Physical Form	Maximum Possession Limit	Proposed Use
			production activities.
n. Depleted Uranium	Metal (Shielding)	67,000 kilograms	For use as shielding in transportation containers, possession and storage.
o. Depleted Uranium	Metal (in slab form)	1 millicurie	Calibration and check of instruments.
p. Cs-137	Sealed Sources	Not to exceed 100 curies total	Calibration and check of instruments.
q. Am-241, Po-210	Sealed Sources	Not to exceed 5 microcuries per nuclide	Calibration and check of instruments.
r. Sr-90	Sealed Sources	Not to exceed 5 millicuries	Calibration and check of instruments.
s. H-3, C-14, Cl-36, Co-60, Tc-99, I-129, Ba-133, Eu-152	Sealed Sources	Not to exceed 1 millicurie per nuclide	Calibration and check of instruments.

Note: This amended license application includes information regarding accelerator produced radionuclides that are currently produced, possessed or stored at the Maryland Heights site.

Section 6

Purpose for which Licensed Materials will be Used

The requested materials will be utilized for manufacturing, processing, packaging, and distribution of radiopharmaceuticals and radiochemicals. The requested materials will also be utilized for research and development of new radiopharmaceuticals and radiochemicals. In addition, some of the radionuclides listed above are produced in particle accelerators; some that are processed into final products and others that are produced incidentally from production of the isotopes of interest. Also, some materials will just be used for possession and storage incident to production activities.

In addition, some radioactive material associated with Mallinckrodt Inc. products will be accepted back from our customers for disposal via our decay-in-storage program and for reclamation of the packaging materials. Additional details associated with this return program are provided in Section 11 of this application for amendment. Also, in accordance with our letter dated December 8, 2005, the Maryland Heights plant may accept small amounts of low-level radioactive material from the Mallinckrodt pharmacies for purposes of consolidation, packaging and offsite transport for disposal.

Finally, some of the authorized material will be utilized to support the radiation protection program. Typical uses in this category would be for instrument calibrations and instrument response checks.

Because the requested possession limits are in excess of the quantities specified in 10 CFR 30.72, we have established an emergency response plan in accordance with 10 CFR 30.32 (i)(3). This plan was previously transmitted to the NRC. We reserve the right to make changes to the plan without prior Commission approval if our Radiation Safety Committee (RSC) determines the changes do not decrease the effectiveness of the plan. If our RSC determines the proposed changes may decrease the effectiveness of the plan, those changes will be submitted to the Commission for approval prior to implementation.

Section 7

Individuals Responsible for the Radiation Safety Program

Executive Management

An organization chart illustrating the reporting relationships of key individuals responsible for the radiation safety program is shown in Figure 7.1. The Site Director is the member of executive management responsible for oversight of the Radiation Safety Program. This individual has ultimate responsibility for the license and activities associated with the license. The individual filling this position serves as a member of the RSC and meetings are scheduled to include this individual when feasible.

The Site Director has the authority to delegate resources for the radiation safety program and to appropriate funds in a timely manner. This individual also has the authority to take necessary actions to ensure radiation safety practices are in accordance with the regulations and conditions of the license.

Radiation Safety Committee

Figure 7.2 illustrates the inter-relationship between Executive Management, the RSC, and the Radiation Safety Officer (RSO). The RSC for this license works with Executive Management and the RSO in implementing the radiation safety program. The RSC also establishes programs and policies for managing the radiation safety program.

The RSC consists of the Site Director, the RSO, and other members representing expertise in all major areas that utilize radioactive materials under this license.

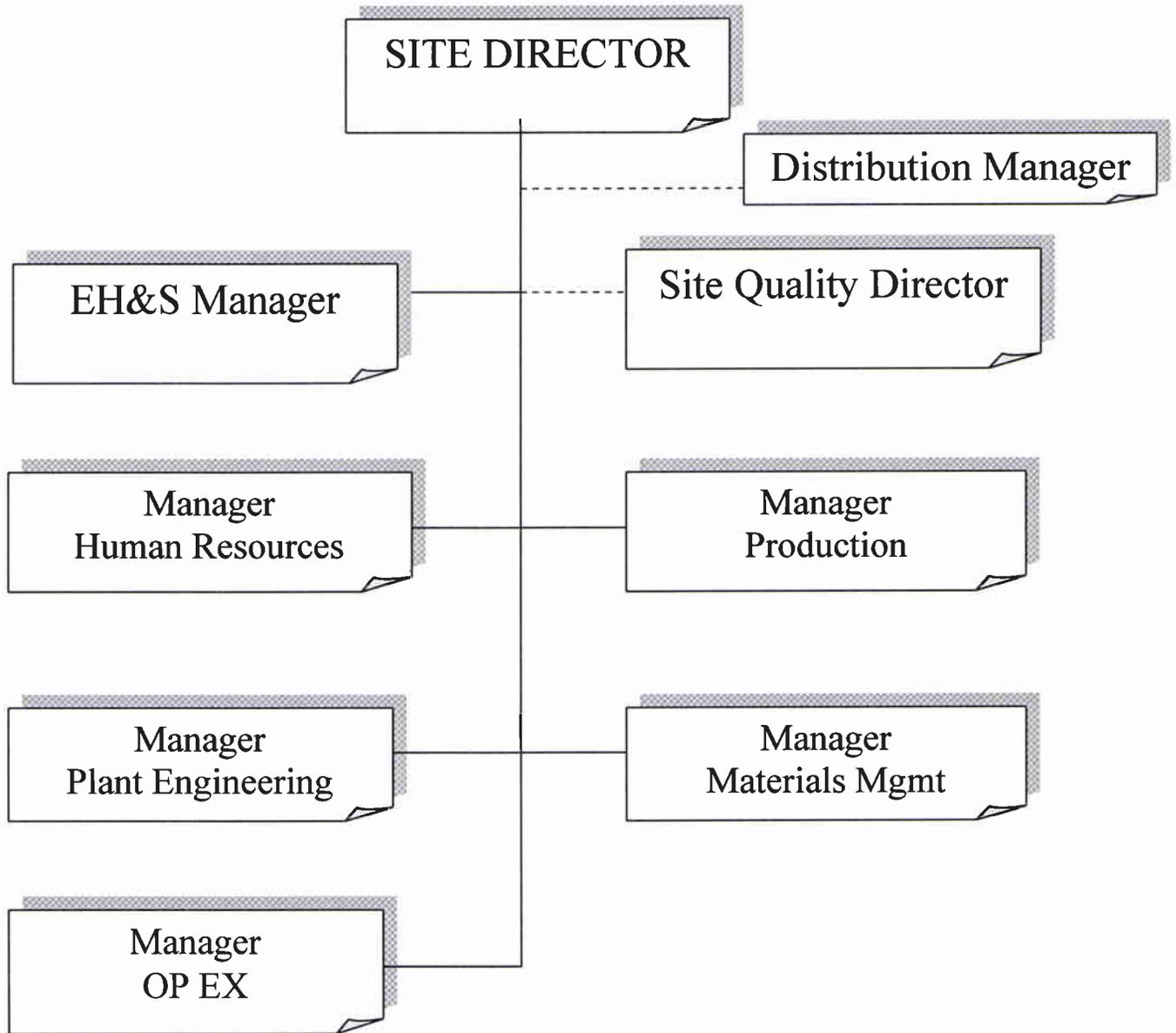
The current RSC consists of individuals filling the following positions:

- Site Director
- Radiation Safety Officer (RSO)
- Health Physics Supervisor
- Manager, Production
- Manager, Maintenance
- Manager, EH&S
- Manager, Corporate Radiological Affairs
- Superintendent, Reactor & Cyclotron Hot Products
- Supervisor, Aseptic Suite
- Supervisor, Radiation Physics
- Senior Process Engineer
- Distribution Technician
- Manufacturing Technician, DTE
- Manufacturing Technician, SHP
- Cyclotron Technician

Section 7

Figure 7.1

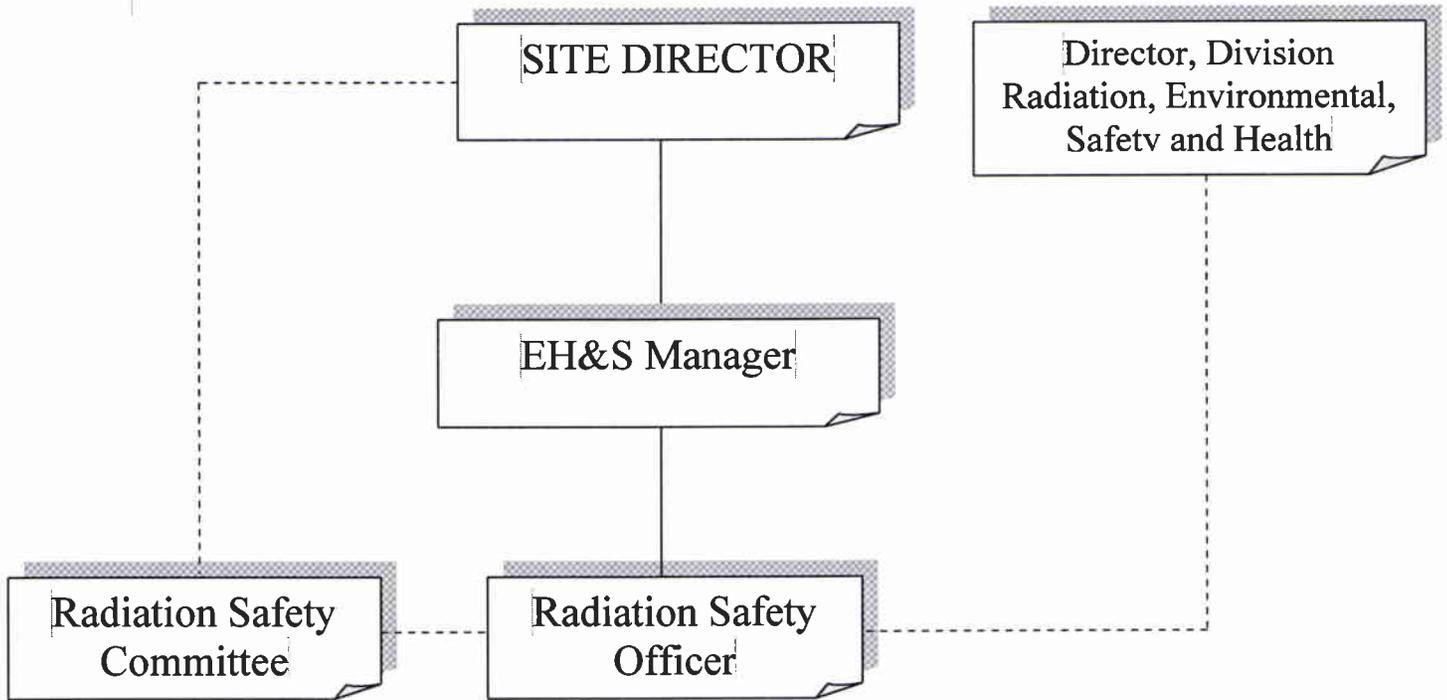
MALLINCKRODT ORGANIZATION CHART



Section 7

Figure 7.2

MANAGEMENT STRUCTURE FOR BROAD-SCOPE LICENSE



----- Program Coordination and Reporting

Section 7

Most of the current RSC members have extensive experience managing programs utilizing large quantities of radioactive material. In addition, most members also have significant experience performing reviews of radioactive material work as required by 10 CFR 33.13(c)(3)(iii).

Criteria for Selecting Members to the RSC

The make up of the committee will include the Site Director, the RSO, and other members representing expertise in all major areas which utilize radioactive materials under this license. The RSC will nominate potential new members and vote on approval of the nominated candidates. They will be evaluated based upon their knowledge of their department's operations and of the site Radiation Safety Program. Care will be exercised to ensure the make-up of the Committee always includes sufficient expertise to provide thorough evaluation of proposed uses of radioactive materials and on-going review of established uses.

The Chairman of the RSC will be appointed by the Site Director. The Chairman will be selected based upon his or her knowledge of radiation safety issues, leadership abilities, and authority by virtue of their position in the organization.

A quorum of the Committee consists of the Site Director or appointed alternate; the RSO or appointed alternate; the Chairman or appointed alternate; and a simple majority of the members. The required members are included when determining whether a simple majority exists.

The RSC may appoint subcommittees to act on behalf of the full committee for specific functions. A subcommittee will consist of a subset of the RSC and may include additional individuals who are knowledgeable of the area being reviewed. Minutes of subcommittee meetings will be reviewed by the RSC and the actions of the subcommittee will be accepted or rejected by the full RSC at the time of that review.

The RSC has the following responsibilities and duties:

1. Review and approve/deny the uses of radioactive material under the broad scope license.
2. Ensure the use of licensed materials is consistent with the ALARA philosophy and program.
3. Make recommendations to the Site Director and other members of Mallinckrodt executive management of matters related to radiation safety.
4. Make recommendations to the Site Director regarding maintenance of the Radiation Safety Program at the Maryland Heights Facility.

Section 7

5. Direct an annual program review.
6. Direct an annual ALARA audit.

In addition, since we are requesting the flexibility to make some program changes and revise procedures previously approved by the NRC, the RSC will:

1. Prior to implementation, review and approve significant program and procedural changes as identified elsewhere in this application for license amendment.
2. Oversee implementation of those revised programs and procedures.
3. Audit operations to determine compliance; and
4. Take appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.

The RSC reviews the proposed use of new radioisotopes and new uses of radioactive material at the Maryland Heights site. The RSC also reviews proposed significant modifications to existing facilities and processes.

When the RSC reviews a proposed use of new radioisotopes, or new uses of radioactive material under our license, they consider, at a minimum, the following items:

1. The purpose of the proposed process will conform to the approved uses of radioactive material under the Mallinckrodt Inc. Broad Scope License.
2. The individual who will supervise the use of the radioactive material will be of Class I status as defined in this license application. The nomination and approval process utilized by the RSC for granting individuals Class I status is described in Section 8 of this application for license amendment.
3. Provisions will be made to handle all solid, liquid, and gaseous waste products associated with the process.
4. Likely radiation doses resulting from the process will be evaluated.
5. The proposed location and facilities will be evaluated for suitability. Consideration will be given to the quantity, radiotoxicity, and volatility of the radioisotopes. The committee will also consider the physical aspects of the proposed facility. This will include the shielding equivalent of the proposed facility, adequacy of ventilation, ease of decontamination, access control, and proximity to unrestricted areas.

Section 7

6. Written protocols will be reviewed.
7. The routes utilized for movement of materials through the site will also be considered.

As part of the review and approval/denial process, the RSC generally requests a cold (non-radioactive) and warm (low activity) run be performed with a member of the HP staff observing. The RSC then reviews the results of these scale-up runs and the observations made by the HP staff. This includes a review of actual dose rates, doses, and airborne concentrations observed during the process. If satisfied, the RSC grants final approval for use of the isotope or process.

The RSC will meet as often as necessary, but not less than quarterly, to ensure the Radiation Safety Program is operating in compliance with our license, applicable regulations, and established procedures.

The RSC meetings will be conducted in accordance with Robert's Rules of Order.

Pertinent details discussed and results of these reviews will be documented in the minutes of the RSC meetings.

Radiation Safety Officer

Implementation of regulatory requirements, license conditions, and the RSC policies is the responsibility of RSO. The RSO is selected by the Site Director. The duties of the RSO, with the assistance of the Health Physics Department, include:

1. Oversight of the site Radiation Safety Program.
2. Monitoring and surveillance of areas where radioactive materials are used and stored.
3. Oversight of ordering and receipt of byproduct material.
4. Oversight of the personnel monitoring program, including determining the need for and the evaluation of bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures exceeding our in-house ALARA goals.
5. Oversight of the training program for radiation workers. This training will be commensurate with potential radiological risk present in their work area.
6. Oversight of the radioactive waste management and disposal program.

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7. Oversight of the decontamination of personnel and facilities.
8. Investigating significant radiological incidents and responding to emergency situations.
9. Maintaining the radiological contingency plan.
10. Maintaining records required to demonstrate compliance with NRC regulations and the Radiation Safety Program.
11. Assist the RSC in the performance of its duties by providing information required to conduct their evaluations.
12. Establish and implement procedures to support the Radiation Protection Program.
13. Evaluate the significance of proposed procedural changes. Approve those changes which are of minor radiological significance. Refer significant proposed procedural changes to the Radiation Safety Committee for review and approval/denial.
14. Evaluate the significance of proposed changes to current authorized processes. Approve changes which are of minor radiological significance. Refer significant proposed modifications to the Radiation Safety Committee for review and approval/denial.
15. Evaluate the significance of proposed modifications to current facilities and equipment. Approve those changes which are of minor radiological significance. Refer significant proposed changes to the Radiation Safety Committee for review and approval/denial.
16. Serve as the primary contact with the NRC and other applicable regulatory agencies for routine communications, licensing, and inspection activities.
17. Audit areas and processes to ensure compliance with applicable NRC regulations, RSC policies, and the site Radiation Safety Program.
18. Restrict or suspend the use and possession of radioactive materials if inadequate radiation safety practices are being demonstrated, or if significant deviations from approved procedures have occurred.
19. Report incidents arising from licensed activities as required by NRC regulations.

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20. Provide consultation on radiological aspects of work performed to personnel at all levels of responsibility in the organization.
21. Maintain a corrective action program to ensure appropriate corrective actions are implemented to address deficiencies identified through events, routine surveillance, and audits.

The RSO for this license is Daniel Hoffman. He has been delegated the authority necessary to terminate any activity involving the use of radioactive material if health and safety aspects appear to be compromised. A copy of the Delegation of Authority is included on the following page. His resume and a table describing details of his experience handling radioactive materials are also provided below.

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Delegation of Authority for Radiation Safety Officer

Daniel Hoffman has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radioactive material. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety concerns; initiating, recommending, or providing corrective action; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of radioactive material. The Radiation Safety Officer is hereby delegated the authority necessary to meet these responsibilities.

The Radiation Safety Officer has the authority to immediately stop any operations involving the use of byproduct material in which health and safety may be compromised or may result in non-compliance with NRC requirements.



Mitzi Pennington
Site Director

24 Aug 09

Date

Section 7

Business Address:
Mallinckrodt, Inc.
2703 Wagner Place
Maryland Heights, MO 63043
(314) 654-7906

Daniel E. Hoffman, CHP, CSP, CHMM

Summary of Qualifications

Dan Hoffman has over 30 years of experience in implementation of environmental and health and safety programs and 25 years of supervisory and program management experience. Experienced in managing EH&S and Radiation Protection programs at manufacturing/industrial facilities as well as environmental remediation and decommissioning projects involving a wide variety of radioactive materials and other hazardous materials.

Professional Experience

Mallinckrodt – Maryland Heights, MO Nuclear Medicine Production Facility

Sep 2007 – Present

Radiation Safety Officer

Manage Radiation Protection Program at a 400-employee nuclear medicine manufacturing site. Oversee all radiological safety aspects of plant operations and radioactive material transportation activities under NRC Broad Scope and Medical Distribution licenses. Ensure compliance with applicable NRC and State of Missouri regulations. Operations include processing of various reactor produced medical isotopes and nuclides produced in the onsite cyclotron units.

Consultant to K2 Environmental Services, LLC

Mar 2007 – Aug 2007

Provided Health Physics support and served as interim Project Health Physicist at Middlesex Sampling Plant FUSRAP site in Middlesex, NJ. Site was undergoing remediation for removal of contaminated soils. Primary contaminants were Ra-226, Uranium, PAHs and lead. Authored 2006 Environmental Surveillance Report which included review and analysis of environmental and occupational radiological exposure monitoring data. Authored Final Status Survey Reports and provided technical assistance in support of radiological surveying activities.

Consultant to Safe Day Consulting

Feb 2006 – Aug 2007

Conducted risk assessments, safety program development, industrial hygiene monitoring and EH&S training at pharmaceutical research laboratory facilities, foundries, printing operations and various other industrial sites. Risk assessments include a review of existing operations and practices, including evaluation of industrial safety, biological, chemical and radiological hazards; personal protective equipment, engineering controls and environmental/waste management practices. Work also included development of lockout/tag-out programs, industrial hygiene air monitoring, noise surveys, EMF hazard evaluations, EH&S audits and occupational safety and health training.

K2 Environmental Services, LLC

Aug 2005 – Jan 2006

Westinghouse FFCF Decommissioning Project, Hematite, MO

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EH&S Manager

Environmental, Health and Safety Manager for decommissioning of the former nuclear fuel fabrication facility. Responsibilities include management and oversight of the environmental, safety and health programs for the decommissioning of the site, which includes removal of contaminated tanks, piping and equipment from the former process buildings. Conduct daily safety briefings and EH&S oversight inspections to ensure conformance to plans, procedures, and regulatory requirements. Also provided independent review/verification of ISOCS radioanalytical measurements of containers and process equipment to quantify residual radioactive materials.

K2 Environmental Services, LLC

Mar 2005 – August 2005

FHWMF Remediation Project

Brookhaven National Laboratory

Upton, NY

Corporate Health Physicist/Health and Safety Mgr

Served as senior K2 project representative for radiological remediation of the Former Hazardous Waste Management Facility (FHWMF) site at Brookhaven National Laboratory (BNL). Responsibilities included management of health physics, waste management/transportation, radiological characterization and final status surveys using the Multi-Agency Radiation Survey and Site Investigation (MARSSIM) Manual guidance. The project involved remediation, packaging and transportation of contaminated soils, sediments and structures at the FHWMF site. The project scope also included packaging and shipment of radiological wastes from the Building 811 remediation project at BNL. Development and oversight of final status surveys and radiological dose assessments using the RESRAD code to verify that site cleanup goals and radiological dose objectives were attained. Primary radionuclides included Cs-137 and Sr-90.

Pangea Group, St. Louis, MO

Nov 1999 – Mar 2005

Vice President and Manager of EH&S Services

Developed and implemented comprehensive EH&S, Radiation Protection and Quality Assurance (QA) Programs and implementing standard operating procedures (SOPs). Applied for and obtained an NRC Materials License for decommissioning and waste management activities at other licensed facilities. Developed Site Safety and Health Programs for various environmental remediation, waste management and construction projects including the Weldon Spring Ordnance Works Closure Project (St. Charles, MO); the Gulf Nuclear Removal Action and Demolition project (Odessa, TX); and the Transportation, Removal and Disposal of Wastes from former USAF Radium Gauge Burial Site (Waco, TX). Responsibilities included acquisition of a mobile Decommissioning License from NRC Region III. Duties included conduct of internal EH&S and QA audits of company operations. Also served as a consultant for various private clients engaged in various radioactive material and waste management operations. Audits for private clients included audits of environmental remediation and decommissioning projects; nuclear medicine production facilities and radioactive material transportation operations.

Jacobs Engineering Group, Inc - Weldon Spring Remedial Action Project, St. Charles, MO

Sept 1987 – Nov 1999

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- **Senior Jacobs Engineering Site Representative/ES&H Manager** – Responsibilities at WSSRAP included management of all environmental, radiation protection, and industrial hygiene programs as well as the occupational medical program, emergency management and response functions, and environmental data verification and validation. Jacobs' staffing levels at the site during this period ranged from 60 to 90 full time technical and professional staff. The success of the occupational safety and health program at the project led to the award of the prestigious Star Status award under the Department of Energy's Voluntary Protection Program. Responsible for development and implementation of industry-leading programs in the area of worker and environmental protection programs and the site's Integrated Safety Management System (ISMS).
- **Deputy Environmental, Safety and Health (ES&H) Manager**- Responsible as the senior technical manager with full time responsibility for ES&H functions and implementation of ISMS at the project site. Total professional and technical staff under the Deputy ES&H Manager averaged about 60 full time personnel. During peak periods of remediation at the site, the total project manpower was in excess of 600 personnel, including subcontractor craft, technical, administrative, and supervisory/management staff. The ES&H Department was responsible for oversight of all field operations across the site. Multiple large-scale remediation operations were being performed concurrently during this period, including demolition of numerous process buildings; excavation and treatment of contaminated wastes and soils; wastewater treatment operations; disposal cell construction; and waste placement activities. Radiation protection, health physics and environmental protection programs were subject to frequent audits on applicable regulatory requirements including the CAA, CWA, RCRA, CERCLA, OSHA and DOE programs.
- **Worker Protection Manager**- Responsible for health physics, industrial hygiene, the on-site radiological laboratory, occupational medical, fire protection and emergency response functions at the project site. Was responsible for compliance with OSHA and DOE regulatory programs for the above functional areas. Managed and coordinated development of programs for personnel, protection, monitoring and training. Responsible for all field oversight functions as well as administrative and program development under the site's Quality Assurance Program.
- **Site Industrial Hygienist**- Responsible for the development, coordination, and administration of exposure monitoring medical and surveillance activities as well as Safety and Health training and development of Safety and Health procedures. Provided technical and managerial support in the areas of process and utility piping systems dismantlement, asbestos abatement, building dismantlement, radiological decontamination activities and containerized chemical consolidation projects.

National Steel Corporation, Granite City, IL Feb 1977 – Sept 1987

Held various technical and managerial positions at National Steel including Manager of Environmental Health, Manager of Environmental Control, Environmental Specialist, Environmental Analyst, and Environmental Technician. Duties included monitoring and evaluating performance of air and water pollution and control systems. Management responsibilities included solid waste disposal facilities and development of solid and hazardous waste handling procedures. Served as Radiation Safety Officer for sealed sources under agreement state license. Responsibilities also included coordination and resolution of environmental matters with Federal, State and local regulatory agencies, acquisition of required permits, and recordkeeping and reporting.

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Sigma Chemical Company, St. Louis, MO - Production Technician June 1976 – Feb 1977

Regulatory Experience

Has working knowledge of US NRC and US Department of Energy regulations, guidelines and directives as well as OSHA and EPA regulatory programs. Experienced in coordinating with various state and Federal regulatory agencies.

Education

University of Missouri-St. Louis, BA/Biology, 1976 (Cum Laude)

Registration/Certifications/Training (partial listing)

Certified Health Physicist, 2000, #4660

Certified Industrial Hygienist, 1987, #3762 (certification lapsed in 2005)

Certified Safety Professional, 1995 #3466, Recertified 2006

Certified Hazardous Materials Manager – Master Level, 1990, #2387

MARSSIM Training – ORISE (Jan 2000)

29 CFR 1910.120 (40 hr & 8 hr Supervisor)

Professional Organization Activity

President, St. Louis Section of the American Industrial Hygiene Assoc. (2006-2007)

Treasurer, Health Physics Society, Decommissioning Section (2004)

Current member of the Health Physics Society

Mr. Hoffman's experience working with, and supervising the use of radioactive materials is detailed in the table below.

Isotope of Use	Amount	Location of Experience	Duration	Type
Natural Uranium and Thorium series radionuclides	Multi-Curie	Weldon Spring Site Remedial Action Project, St. Charles, MO	12 years	Radiological Site Remediation
Am-241, Cs-137	Millicuries	Gulf Nuclear Site, Odessa, TX	8 months	Radiological Site Remediation
Cs-137, Sr-90	Multi-Curie	Brookhaven National Laboratory, Upton, NY	6 months	Radiological Site Remediation
Low-enriched U-235	Multi-Curie	Westinghouse Hematite Site, Festus, MO	6 months	Radiological Site Remediation
Atomic #'s 3-83, Depleted Uranium	Multi-Curie	Mallinckrodt, Maryland Heights, MO	1½ years	HP Support of Manufacturing

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Training for Individuals Working in or Frequenting Restricted Areas

A training program has been established at the Mallinckrodt, Maryland Heights site to insure that initial and refresher training is provided to all individuals who are granted unescorted access to the site or who may come in contact with radioactive materials. In accordance with 10 CFR 19.12, such training will be commensurate with the level of radiological safety required for the type of work being performed.

Training will be provided by lecture, videotape, written handouts, computer, or other media. This training will be provided by an individual knowledgeable of Health Physics and the Radiation Safety Program at the Maryland Heights site. In general, training will include a written examination or proficiency test to insure retention of the topics presented.

Individuals granted unescorted access to the site will be required to attend recurrent refresher training.

Modifications to the training program described below will be evaluated by the Radiation Safety Officer. Changes deemed to be significant will be reviewed and approved/denied by the Radiation Safety Committee prior to implementation.

The following levels of training will be provided to individuals entering our site.

Visitors

Untrained visitors will not be allowed access to restricted areas. Untrained visitors entering the Maryland Heights site beyond the reception area or guard houses are required to be entered into the site security system. They are required to be under the constant escort of an individual who has unescorted access to the site. Exceptions may be made for individuals that will remain in their vehicles while onsite. This may include selected truck drivers or delivery personnel, excluding those carrying radioactive materials. Anyone entering the site shall be informed that radioactive materials are used at the site.

Class IV Level of Training

Except as noted above, any individual who requires unescorted access to our site, but who will not enter posted radiation or radioactive material areas, will be required to attend an initial training course. This training course will cover general awareness, security, emergency response, and radiation safety aspects associated with the work they will perform at the Maryland Heights site. This training session will also provide details regarding the limitations of their access.

Note: In certain circumstances such as cyclotron maintenance augmentee work,

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Class IV employees may be provided with additional radiation safety training that will qualify them to perform work under direct supervision in restricted areas. Such training will be documented and will comply with 10 CFR 19 requirements.

Class III Level of training

An individual who may be escorted into posted radiation areas will be required to attend the Class IV training session, as well as receive additional training associated with risks and biological effects associated with exposure to ionizing radiation. These individuals may be escorted into a radiation area by any radiation worker who has achieved a Class II or Class I level of training. In addition, they may handle radioactive materials under the direct (line-of-sight) supervision of a Class I employee.

Class II Level of Training

Individuals who require unescorted access into posted radiation areas or who will work with radioactive materials independently are required to attend a more detailed training session. This will include descriptions of radiation, radioactivity, risk, and biological effects associated with exposure to ionizing radiation. This training will also include information associated with principles and practices associated with radiation safety such as the ALARA principle and techniques available to ensure exposures are maintained ALARA. In addition, detailed information will be provided related to specific procedural requirements at the Maryland Heights site such as emergency procedures, control of potentially contaminated materials, disposal of radioactive waste, survey meter availability, radiation level monitoring, radiation contamination monitoring, and on-site incident reporting requirements. Finally, hands on training will be provided related to proper donning and removal of personal protective equipment (PPE) for contamination control and use of radiation detection instruments utilized at the Maryland Heights Facility.

Class I Level of Training

Individuals who will oversee the activities of other radiation workers require a Class I level of training. A Class I employee must be familiar with the scope of work being performed and knowledgeable of appropriate emergency response actions, will be on site any time radioactive materials are being handled. Class I trained employees will provide initial coordination of response activities following radiological incidents.

The Radiation Safety Committee will review and approve all candidates for Class I training. They will consider raising an individual's classification to Class I provided the following conditions are met:

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- The individual must have a minimum 12 hours of college level science, or 2 years of technical military training, or 2 years of technical vocational school, or equivalent experience.
- The individual must have at least three months experience working with the types and quantities of radioactive material which will be used under their supervision.
- Beyond their Class II training, they will also be required to receive additional specialized training regarding regulatory requirements, license conditions, the site Radiation Safety Program, and investigative/corrective measures to be taken in the event of radiological incidents.

Section 9

Facilities and Equipment

This section provides an overview of the facilities and equipment at the Mallinckrodt Inc., Maryland Heights, Missouri Facility. Section 9.1 is a description of the site and buildings where radioactive material is used or stored. This section also includes a description of important aspects of the ventilation system associated with each process area. Section 9.2 is a description of the special application facilities. These facilities include radioactive waste processing facilities, hot cells, radioactive waste storage facilities, and areas processing 100 millicuries or more of radioactive material per process. Section 9.3 includes information concerning our use of sealed sources and their storage locations. Section 9.4 describes the change control process that is used for changes to facilities and/or equipment, including RSO and RSC reviews.

9.1 Description of Site and Buildings

The Maryland Heights Facility, situated on approximately 20 acres, consists of 12 major structures designated as Buildings 100, 150, 200, 250, 250A, 300, 400, 500, 500A, 600, 700 and 800. Figure 9-1 is a plot plan of the Mallinckrodt site detailing the locations of major structures. The main site, encompassing the above referenced buildings, not including Building 150, is completely enclosed by a perimeter fence. Access to the site is controlled with the use of an electronic card reader access system. Site access is also controlled by a continuous security force that controls access to the site via the main gate north of the site. The security force performs routine rounds to provide additional assurance of plant security.

Building 150 is located across Wagner Place, southeast of the main site, and is also enclosed by a perimeter fence. Access to this area is also controlled with the use of an electronic card reader access system.

Description of Buildings

All buildings on our site are constructed of concrete block walls with metal roofs. The one exception is Building 400 which has metal walls. Building 400 has extensive solid concrete block bunkers erected within the building for storage and segregation of packaged Mo/Tc Generators prior to shipment off-site. The concrete block walls act as shielding to minimize radiation exposures to personnel occupying nearby areas.

The size of these buildings and the activities performed in each of them are summarized in Table 9-1.

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Table 9-1 Description of Buildings at the Mallinckrodt Maryland Heights Facility

Building	Square Footage	Use	Current Radioactive Work
100	19,000	Offices; Production, Health Physics, Purchasing, Environmental Safety, and Maintenance. Quality Control Radioactive storage	Sealed sources used for calibration of survey instrumentation; two rooms in the basement. QC elutions of DTE generators.
150	100,000	Receiving, Warehouse, Generator Reclamation, Quality Control	Decay-In-Storage (DIS), breakdown, and reclamation of Mo/Tc generators returned from customers.
200	25,000	Quality Control Labs; Offices for Administration, Accounting, and Regulatory Compliance	Quality control testing of raw materials, in-process, and finished product radioactive materials.
250	2,300	Storage of radioactive waste for decay	Storage
250A	2000	Storage of radioactive waste for decay	Storage
300	15,000	Finished product storage; offices for Traffic, Distribution	Storage, packaging, labeling, and shipment of radioactive materials. All contained sources.
400	10,000	Packaging and shipping of products	Storage, packaging, labeling, and shipment of radioactive materials. All radioactive material is contained.
500	5,000	Storing solid and liquid radioactive waste; decayed waste disposal; reclamation (non-generators)	Processing and storage of radioactive waste materials including low activity uncontained sources (waste materials).
500A	700	Storage of liquid radioactive waste	Liquid waste storage.
600	64,000	Processing and production; receiving and warehousing; receiving incoming radioactive materials; offices for Production and support staff	Radioactive raw material receipt, processing, in-process QC testing, dispensing, packaging into leads safes, and generator production all occur in Building 600.
700	35,180	Processing and production; warehousing	Cyclotron operations, target irradiations/transfer; radiochemical processing of irradiated targets.
800	8,600	Processing and production; offices for Production and support staff	Cyclotron operations, target irradiations/transfer; spent target waste storage.

Building 100

This building currently houses primarily office space and non-radioactive production activities. Two sealed calibration sources (Cs-137) are stored and used in the basement of Building 100 in the Health Physics Area. Both are used for calibration of instruments and dosimetry devices. In addition, one room in Building 100 is utilized for conducting studies associated with Mo/Tc generators.

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The room has a number of auxiliary shields to house generators being studied as part of Quality Control investigations.

Building 150

Currently, the only radioactive work in Building 150 deals with the receipt, decay and reclamation of returned expired Mo-99/Tc-99m generators. Expired generator columns are stored, while reusable components are cleaned and returned to inventory. All radioactive work currently occurs in a two room area in the southeast corner of the building. Access to this area is controlled through an electronic card reader access system.

Building 200

Radioactive materials are utilized primarily in the Quality Control laboratories. In these laboratories, samples of each production lot are tested for a variety of parameters including radionuclide concentration, radionuclidic purity, radiochemical yield, and sterility. In addition, finished products being held as Quality Control "reserve" samples are stored in the reserve storage room. This storage area is within the main Quality Control assay laboratory. Finally, biological waste containing small amounts of activity is stored in a storage freezer as part of our waste decay-in-storage program.

Building 250/250A

These buildings are used for decay-in-storage of radioactive waste materials. Building 250 is designated for storage of waste containers with elevated contact dose rates; whereas Building 250A is designated for storage of waste containers with lower contact dose rates. Radioactive wastes are stored in these buildings for a period of several months or longer until they can be processed in accordance with our radioactive waste disposal program.

Building 300

Radioactive products are packaged, surveyed, labeled, and stored in this building until they are offered for shipment.

Building 400

Mo-99/Tc-99m generators which have been assembled into shields are moved into Building 400 for final packaging, labeling, surveying, and shipping. Other products in Building 400 are in the form of labeled packages prepared for shipment, awaiting pick-up by a carrier. Building 400 has loading dock access to allow ease of loading trucks with packaged radioactive products.

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Building 500 and 500A

Building 500 is the location where solid radioactive waste is processed, stored, and surveyed for unrestricted release. Solid wastes are stored in bags, 55 gallon drums, or pails. Some wastes, depending on activity levels and half-life, are shredded in one of three shredding machines. Low level bagged radioactive wastes are compacted in a barrel compactor. Decay-in-Storage (DIS) wastes are surveyed in a low background area to determine if they can be disposed of in non-radioactive dry solid waste containers. Building 500 also serves as a decay-in-storage area for expired finished goods and for cleaning and returning reusable components to inventory. Expired finished goods, after sufficient decay, are removed from their lead shields and placed into the normal radioactive waste stream for additional processing.

Building 500 also houses radioactive liquid waste storage tanks and acts as the main collection point for all radioactive drains on site. Liquid waste enters one of three compartmentalized retention tanks from radioactive waste drains in Buildings 200, 500, 600, 700, and 800. Each of the three tanks has a capacity of 5,000 gallons. Liquid waste in these three tanks can be pumped to one of two additional four-compartment tanks in Building 500A. Each of these tanks has a capacity of 10,000 gallons. Liquid radioactive waste is transferred from Building 500 to Building 500A by use of an internal piping system and a manually activated pump.

The expired finished radioiodine products are stored in a ventilation controlled area within building 500. Low dose-rate waste is transported to Building 500 where it is compacted into drums. Reusable component parts of finished products that have decayed to background levels are reclaimed or recycled. The radioactive components of these expired products are compacted or shredded with other radioactive waste.

Building 600

This building is the main production building. Incoming radioactive materials are received and surveyed at the Building 600 activity check-in area. In addition, cyclotron produced radioactive materials are received from the Cyclotron Chemistry Lab. The radioactive material is then transferred to various hot cells, glove boxes, or hoods, depending on the nuclide involved. Each radionuclide is currently handled in separate specially designed facilities within Building 600. A general building overview showing the relative locations of all of the labs is included as Figure 9-2. Table 9-2 indicates the radionuclides currently being processed in the various labs in Building 600. Floor plans of the larger processing labs, including the Iodine Labs, Generator Production Lab, and R/A Processing/Dispensing Labs are included as Figures 9-3, 9-4 and 9-5. Major equipment in these areas is further detailed in Section 9.2.

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Table 9-2 Miscellaneous Nuclide Processing in Building 600 by Room Number

Nuclide	Possession Limit (Ci)	Concentrate Processing	Dispensing	Intermediate Storage	Packaging
Xe-133	800	3A	3A	N/A	3A
P-32	100	3A	3A and Autoclave (7H)	7B	7F
Cr-51	100	3A	6B	7A	7A
Tl-201	350	6B	6B	7A	7A
Ga-67	300	6B	4C	4C	4C
I-123	10	4C	4C	4C	4C
In-111	30	6B/7A	6B/7A	6B/7A	7F

Buildings 700 and 800

Buildings 700 and 800 house our cyclotrons used for production of radionuclides. These buildings are used for cyclotron operations and target irradiations, radiochemical processing of cyclotron targets, and target recovery and preparation.

Additional information about the six cyclotron units is provided in the following Table 9-3 below.

Table 9-3 General Information on Maryland Heights Cyclotrons

Cyclotron Designation	Location	Year of Installation	Beam Configuration	Maximum Beam Energy
MC-40	B700	1984	Internal	40 MEV
CS-30-1	B700	1980	Internal	27 MEV
CS-30-2	B700	1990	Internal	27 MEV
IBA	B800	1994	External	30 MEV
TR30/1	B800	2004	External	30 MEV
TR30/2	B800	2006	External	30 MEV

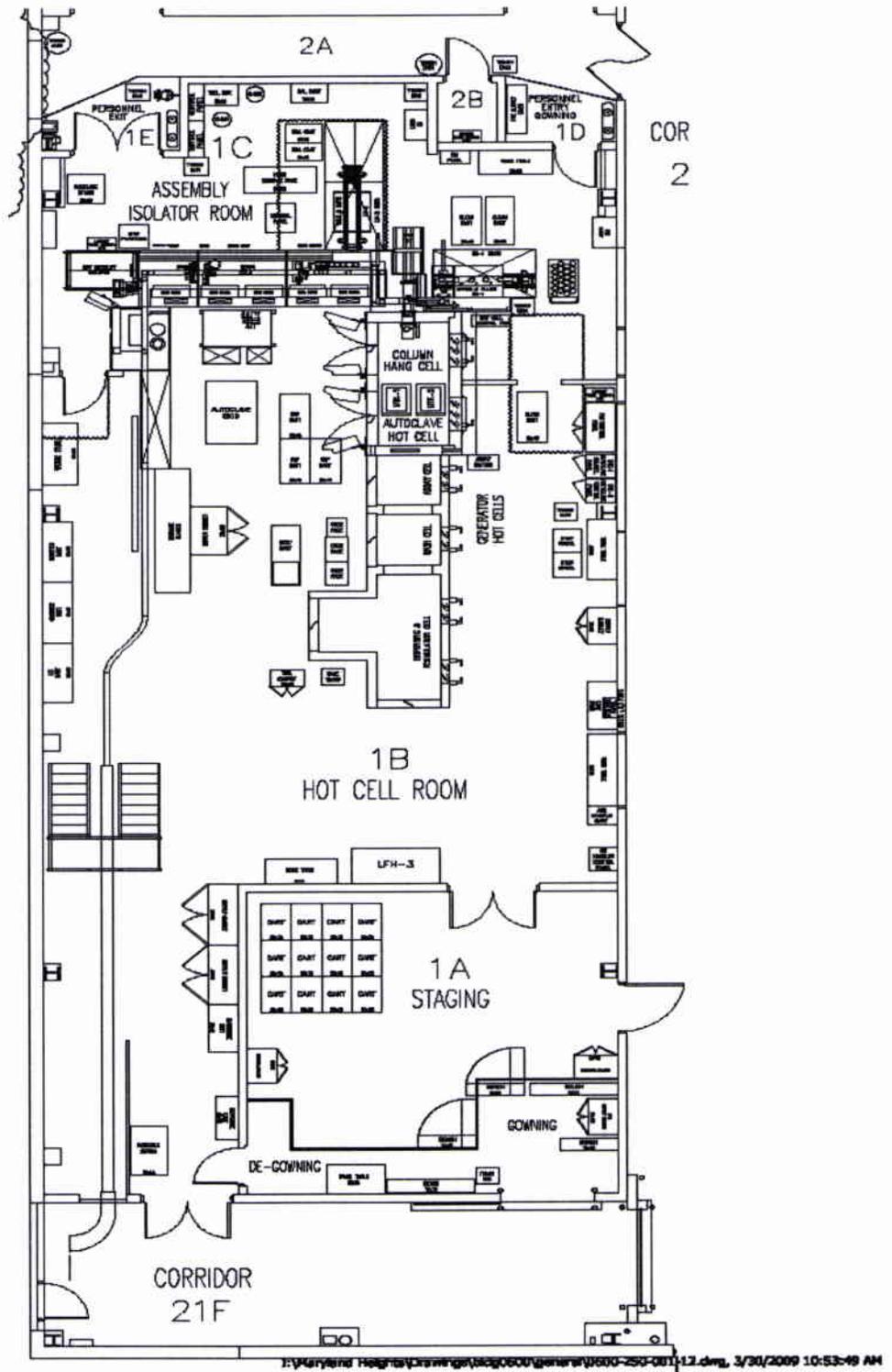
Floor plans for Buildings 700 and 800 are provided in Figures 9-6 and 9-7, respectively. The location of the cyclotrons and ancillary equipment is indicated on these plans. Also shown in Figure 9-6 In addition is Lab 710 (Target Prep & Recovery) and Lab 711 (Target Chemistry and Assembly). These are the primary processing areas for cyclotron targets.

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Figure 9-3 Lab 3A (I-131 Lab) and 4C (I-123 Lab) Plan View

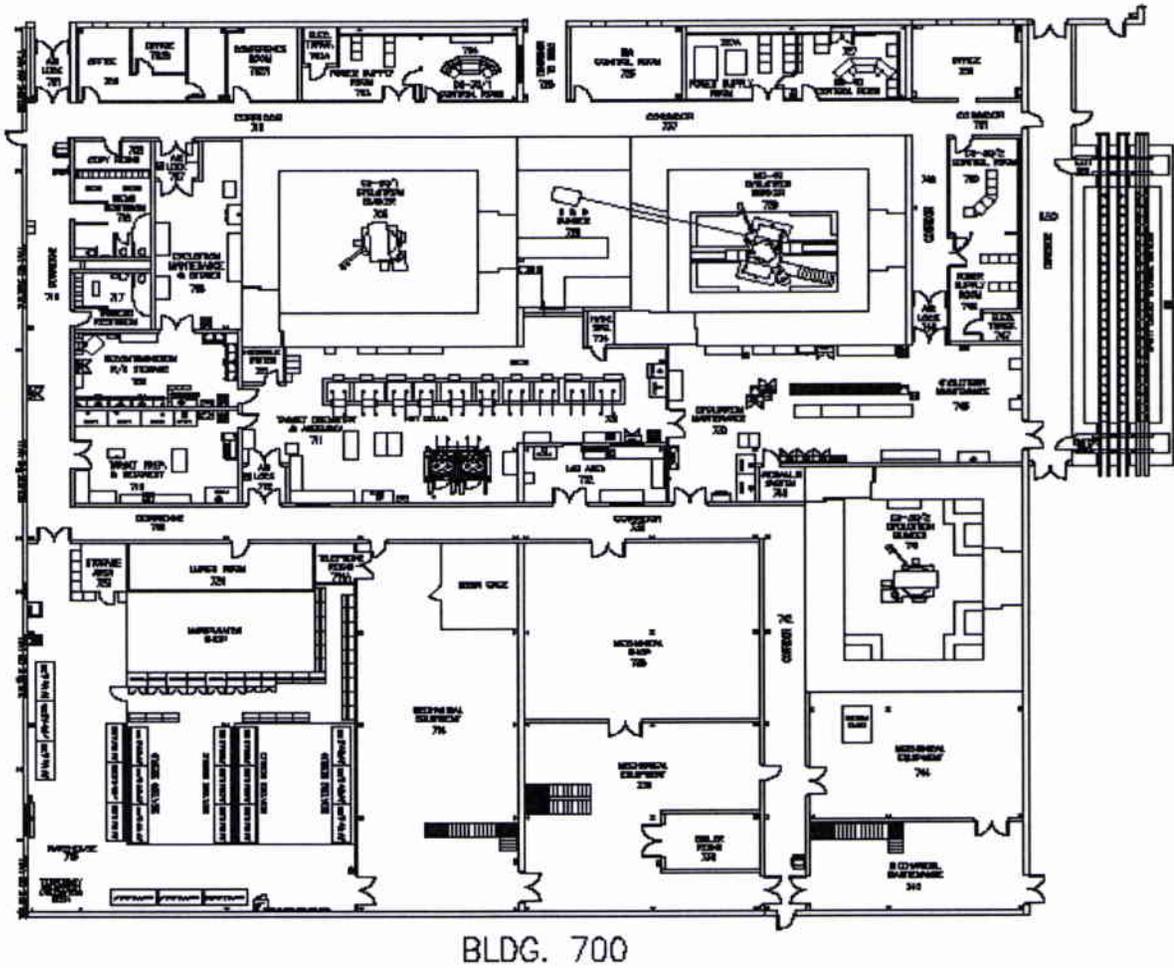
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Figure 9-4 Lab 1B Generator Lab Plan View



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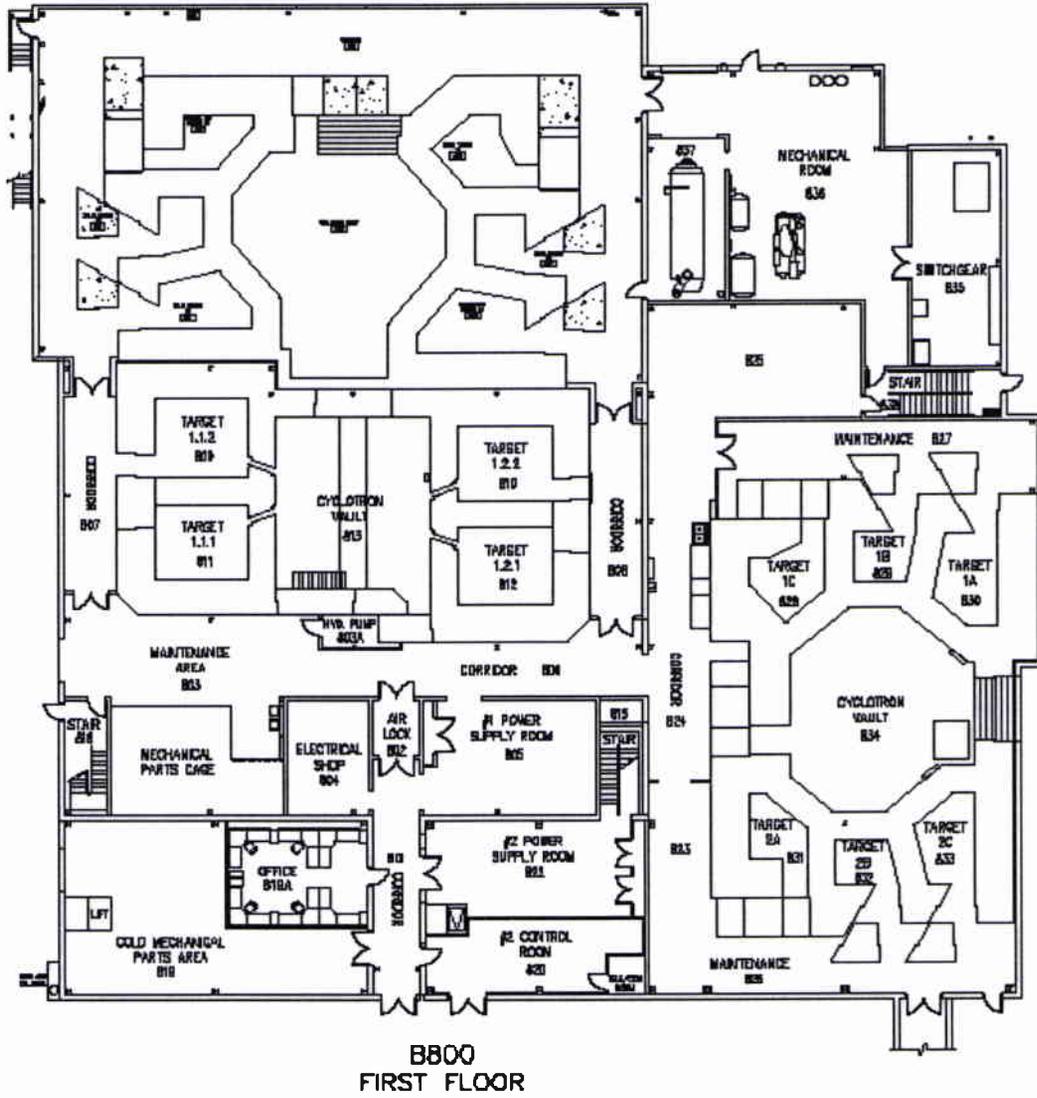
Figure 9-6, Building 700 Plan View



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Figure 9-7 Building 800 Plan View



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Ventilation System and Stack Information

In general, areas where radioactive materials are handled have sophisticated ventilation systems specifically designed for work associated with volatile radioactive materials. Air from special facilities and potential airborne radioactivity areas within these buildings is exhausted through HEPA and/or charcoal filters. These air handling systems are equipped with sensors to monitor pressure differentials and/or airflow. In the event one of these parameters fall outside of pre-determined ranges, several alarms are actuated to alert personnel of system degradation. A highly visible revolving beacon will alert personnel in the affected laboratories. In addition, visible and audible alarms will be actuated in both the Health Physics Office and the continuously manned security station. Details associated with the air treatment systems for specific buildings are included in the paragraphs which follow.

Building 200

On the first floor in Building 200, laboratories in which radioactive materials are handled are equipped with fume hoods and gloveboxes connected to air exhaust/filtration systems. The air from these systems is filtered through HEPA and/or charcoal before release. On the ground floor, the areas in which radioactivity is handled are kept under negative pressure by air exhaust systems. If these air handling systems lose pressure or airflow, the previously mentioned alarms are activated.

Building 300

The distribution areas in Building 300 are kept under negative pressure with respect to adjacent areas. The system that keeps this area under negative pressure is exhausted through charcoal filters. If these air handling systems lose pressure or airflow, the previously mentioned alarms are activated.

Building 400

Building 400 has no radioactive air exhaust system since only sealed, finished products are handled there.

Building 500

The enclosures in which solid wastes are shredded, compacted and stored in Building 500 are connected to an air exhaust filtration system. The filter bank for this system contains both HEPA and charcoal filters. An electronic system monitors air flow through the exhaust system. If these air handling systems lose pressure or airflow, the previously mentioned alarms are activated.

Building 600

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The I-131 and Mo-99/Tc-99m hot cells in Building 600 have redundant ventilation systems. If one system fails, the backup system is automatically actuated. The filter banks, located in the penthouse of Building 600, have appropriate filters in series. All systems in this building except the Xe-133 vent stack, the DTE generator hot cells and the DTE assembly line isolators discharge through a common stack penetrating the penthouse roof. The DTE generator hot cells and assembly line have a separate dedicated stack. Each system is equipped with backflow dampers before and after the filter banks. The dampers are actuated upon loss of airflow through the system, thereby stopping releases and back-flow. Each system is also connected to a central air flow monitoring system. If these air handling systems lose pressure or airflow, the previously mentioned alarms are activated.

All ventilation system alarms and backflow dampers are connected to the emergency power supply.

As a result of these air exhaust systems, all radioactive material process areas are under negative pressure. The hot cells are also at negative pressure with respect to the process areas. The pressure differential between the inlet and the outlet end of the exhaust filter banks is continuously monitored and the pressure differential is displayed on the photohelic units located near the filter banks. If there are any changes from the predetermined set points, an alarm is activated at the local panel, the guard station, and at the Health Physics alarm monitor.

Information related to the radioactive exhaust systems and radionuclides associated with each stack is provided in Table 9-3.

Table 9-4 Radioactive Exhaust System and Radionuclide Release Information

Stack Number	Building/Lab	Current Radioactive Material Handled	Filter Sequence	Filter Arrangement
Stack #1	Building 200 Q.C. Radiation Physics Lab Hoods	All	Pre-filter HEPA	2H x 3W
Stack #1	Building 200 Room 222C	All	Pre-filter HEPA	1H x 1W
Stack #2	Building 250 Q.C. Radiation Physics Hold Room	All	Pre-filter HEPA Carbon	1H x 2W
Stack #3	Building 300 Dispensing Hold Room	I-131	Pre-filter HEPA Carbon	1H x 2W

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Stack #4	Building 500 Radioactive Waste Handling/Reclamation	All	Pre-filter HEPA Carbon HEPA	2H x 1W
Stack #5	Iodine Lab, Gloveboxes and hoods; AFB-6	I-123, I-131, Xe-133, P-32	Pre-filter HEPA Carbon Carbon HEPA	1H x 3W
Stack #5	Iodine Lab, Gloveboxes and hoods; AFB-6A	I-123, I-131, Xe-133, P-32	Carbon	1H x 1W
Stack #5	Standards Lab Iodine Capsule Lab; AFB-7	All	Pre-filter HEPA Carbon Open HEPA	2H x 3W
Stack #5	Decon, AFB-8	All	Pre-filter HEPA Carbon Open HEPA	1H x 3W
Stack #5	R/A Fill Lab; AFB-9	Ga-67, In-111, Pb-201, Tl-201	Pre-filter HEPA Carbon Open HEPA	1H x 1W
Stack #5	R/A Packaging Lab; AFB-10	Ga-67, In-111, Tl-201	Pre-filter HEPA Carbon Open HEPA	2H x 3W
Stack #5	Misc R/A Processing Lab Mini-Cells, AFB- 11, 12	Ga-67, In-111, Tl-201	Pre-filter HEPA Carbon Carbon HEPA	1H x 1W
Stack #5	Corridor 2A	All	Pre-filter HEPA Carbon Carbon HEPA	1H x 2W
Stack #5A	Building 600 Generator Lab Hot Cells; AFB-1,2 (Redundant)	Mo-99, Tc-99m	Pre-filter HEPA	1H x 1W

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Stack #5A	Iodine Lab Hot Cells; AFB-4,5 (Redundant)	I-131	Pre-filter HEPA Carbon Carbon Carbon HEPA	1H x 1W
Stack #6A	Building 700 CS-30-1 Cyclotron, Target Chemistry Lab Hot Cells, Hoods, Gloveboxes, Decon Lab, Target Prep Lab, and CS-30 Maintenance Lab	Ga-67, In-111, Pb-201, TI-201 and other incidentally produced radionuclides	Pre-filter HEPA Carbon Carbon HEPA	1H x 2W (700-1) 2H x 2W (700-2) 2H x 2W (700-3)
Stack #6B	Building 700A MC-40 Cyclotron, MC-40 Maintenance Lab, Counting Lab Hood	Ga-67, In-111, Pb-201, TI-201 and other incidentally produced radionuclides	Pre-filter HEPA Carbon Carbon HEPA	3H x 3W (700A-1) 1H x 2W (700A-2)
Stack #6B	Building 700B CS-30-2 Cyclotron; CS-30-2 Maintenance Lab	Ga-67, In-111, Pb-201, TI-201 and other incidentally produced radionuclides	HEPA Carbon Carbon HEPA	1H x 3W (700B-1) 1H x 1W (700B-2)
Stack #7	Building 800 IBA Cyclotron; 4 Target Bunkers; IBA Maintenance Lab	Ga-67, Pb-201, TI-201 and other incidentally produced radionuclides	Pre-filter HEPA Open Open HEPA	3 x 3W
Stack #8	Building 800 TR-30/1 Cyclotron; 6 Target Bunkers	TI-201, Pb-201 and other incidentally produced radionuclides	Pre-filter HEPA Open Open HEPA	4H x 3W
Stack #9	Building 800 TR-30/2 Cyclotron; 6 Target Bunkers	TI-20, Pb-201 and other incidentally produced radionuclides	Pre-filter HEPA Open Open HEPA	4H x 3W
Stack #10	Spent Target Storage Bunker (STSB)	Ga-67, In-111, Pb-201, TI-201 and other incidentally produced radionuclides	Pre-filter HEPA Open Open HEPA	1H X 1W

Filter Arrangement: 1H x 2 W means one filter high and two filters wide within the filter bank.

9.2 Description Of Special Application Facilities

Iodine-131 Hot Cell

This hot cell is located in Lab 3A, Iodine Lab, located at the SW corner of Building 600. The hot cell is constructed with eight inch thick steel walls with lead

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glass windows, thickness equivalent to the steel thickness for shielding. The hot cell is broken into two sections divided by a vertical remote operating shielded door. The back of the hot cell has two sets of overlapping steel doors to allow access for maintenance. The hot cell has a dedicated ventilation system that is described above and has redundant ventilation systems with two fans and two sets of filters. One fan and one filter bank is the minimum configuration at any time. The hot cell is directly attached to the I-131 therapy solution processing glovebox through hot cell wall penetrations. Refer to Figure 9-3 for the lab placement and configuration of the hot cell.

Mo/Tc-99m Hot Cell

This hot cell is located in Lab 1B, Generator Production Lab, located at the SE corner of Building 600. The main hot cell is constructed with eight inch thick steel walls with lead glass windows, thickness equivalent to the steel thickness for shielding. The DTE hot cell section is constructed with ten inch thick steel walls with lead glass windows, thickness equivalent to the steel thickness for shielding. The hot cell is currently broken into five sections divided by three vertical remote operating shielded doors and one pair of pass-through autoclaves. The back of the hot cell has five sets of overlapping steel doors to allow access for maintenance. One side of the main hot cell has a set of overlapping steel doors to allow for material transfer. The hot cell has redundant ventilation with two fans and two sets of filters for the DTE line and two fans for the UTK hot cell section. One fan and one filter bank is the minimum configuration at any time. Refer to Figure 9-4 for the hot cell configuration and placement in the lab.

Miscellaneous Radioactive Materials Processing

Products containing Ga-67, In-111 and Tl-201 are processed, dispensed, sterilized and packaged in Building 600, Rooms 6B, 7A, 7H and 7F, respectively. These areas are known as the R/A Processing Lab, R/A Dispensing Lab, R/A Autoclaves and R/A Packaging Area. Small shielded gloveboxes or "minicells" are used for processing these of these materials. They provide shielding and are also ventilated to a filter bank. Raw material for I-123 products is diluted in a dedicated glovebox in the Iodine Lab (3A). I-123 capsules are processed, dispensed and packaged in Room 4C.

Radioactive Waste Processing and Storage Facilities

Solid radioactive waste originating from several sources is stored and processed on-site. These sources include product processing and handling, quality control testing, reclamation activities, and our return waste program

Most waste processing occurs in Building 500. This building currently contains three shredding machines, a barrel compactor, sorting tables for reclamation and surveying Decay-in-Storage (DIS) wastes prior to disposal, storage racks used

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for DIS of expired finished goods, a locked, ventilation controlled high radiation area used for DIS of expired iodine finished goods and miscellaneous radioactive material storage, shipping container cleaning and preparation area, and the main liquid radioactive waste collection tanks. Wastes that are processed in this building are low dose-rate wastes.

Buildings 250 and 250A are used as DIS areas for most radioactive wastes collected from the site laboratories and hot cells. All high dose-rate waste is currently stored in Building 250 while low dose-rate DIS storage wastes are currently stored in Building 250A. The waste placement within this building is rotated to minimize exposures to personnel and allow the maximum decay of wastes prior to further processing. The walls and ceilings are constructed to maximize shielding and minimize personnel and public exposures.

Building 150 is used for the reclamation of return Mo/Tc generators. The expired columns from these reclamation activities are currently stored within the building 150 reclamation area. The columns are stored in a shielded bunker within the reclamation processing area. The column storage area is key-controlled due to the elevated dose rates. Periodically, these columns are shipped off-site for disposal.

Laboratories Processing 100 millicuries or more of Radioactive Material per Process

Processing may include quality testing, dilutions, dispensing, packaging product into shields, generator assembly and generator reclamation. Many of the laboratory areas are designed to minimize external exposures utilizing hot cells, gloveboxes and minicells. Ventilation systems, previously described, minimize the potential for airborne radionuclides and provide a controlled, filtered work environment within many laboratories. Table 9-5 describes those areas within each building that are currently utilized for processing more than 100 millicuries at a time.

Table 9-5 Areas Currently Housing Processes Involving > 100 mCi

Building	Room Number	Current Uses
100	136A	Storage and elution of Mo/Tc generators. The contained elution samples are transported to the radiation physics lab (222C) for analysis.
150	1501	DIS for packaged, returned Mo/Tc generators.
150	1502	Reclamation of returned Mo/Tc generators and expired column storage.
200	250	Atomic absorption preparation and analysis of radioactive samples.
200	247A	HPLC preparation and analysis of radioactive samples
200	232A	Storage and manipulation of finished product samples. Mainly stored in incubators for microbiological testing.
200	240/241	Sterility preparation and analysis of finished products.
200	230	Bacteriological endotoxin preparation and analysis of finished products.
200	222C	Radiation physics testing including: radiochemical purity, radionuclide

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Building	Room Number	Current Uses
		concentration, chromatography and assay. Reserve samples are also stored in this area.
600	10A	Satellite to the radiation physics laboratory. Testing: radionuclide concentration and assay. Reserve samples are also stored in this area.
600	4C	Preparation and manufacture of iodine-123 capsules.
600	3A	Preparation and dispensing of chromium-51. Preparation and dispensing of iodine-131 capsules and oral solution, xenon-133 gas, and phosphorus-32 products. I-123 raw material is prepared in this lab. Iodine-131 products are placed into lead safes within this lab.
600	6B	Preparation of gallium-67, indium-111 and thallium-201.
600	7A	Dispensing of gallium-67, indium-111 and thallium-201.
600	7H	Terminal autoclaving of finished products.
600	7F	Labeling and placing finished product vials into lead safes.
600	1B	Dilute molybdenum-99 for use in loading generator columns. Assemble and test/operate generators prior to shipment.
600	1C	Packaging of Mo/Tc generators; collection of QC samples; product assay.
700	711	Stripping of cyclotron targets and separation of gallium-67, indium-111 and thallium-201 from stripping solutions. Above work processes are performed in ventilated hot cells.
700	709	Storage for decay of spent stripping solutions prior to recovery of target metals.
700	710	Preparation of targets and recovery of target metals from spent stripping solutions.
700/800	Cyclotrons	Irradiation of electroplated targets; transfer of irradiated targets to the hot cells in 711 (Cyclotron Chemistry).

9.3 Sealed Sources

Sealed sources are used for instrument calibrations and instrument source checks in support of the procedures for calibration and use of radiological instrumentation. Procedures are in place to ensure that sealed sources, excluding exempt sources, are wipe-tested for contamination at least every six months. Table 9-6 indicates the storage location and current use for each non-exempt sealed source currently stored on-site.

Table 9-6 Sealed Sources and Storage Locations

Building	Activity	Current Location	Model/Serial Number	Current Uses
100	5 Curies Cs-137	149F	JL Shepard Model 28-8A Serial Number 10079	Instrument calibrations.
100	1 Curie Cs-137	145	JL Shepard Model 28-6A Serial Number 10098	Instrument calibrations.
100	0.5 millicurie Sr/Y-90	146	Harshaw/Bicron 6600E Serial Number B053	None; this source was removed from a Harshaw 6600 TLD reader that is no longer onsite.

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100	0.5 millicurie Depleted Uranium	149F	Eberline S/N 5539-05	Instrument calibrations.
200	271 μ Ci Cs-137	245	IPL Model RV-137-250U Serial No. 644-72-8	Source checks.
200	258 μ Ci	247A	IPL Model RV-137-250U Serial No. 788-3-9	Source checks.
200	203 μ Ci	222	IPL 644-69	Source checks.
400	20 millicurie Cs-137	B400 Bunker	IPL Model HEG-137 Serial No. MM-310	Source check and calibration for the generator package monitoring system.
400	5 millicurie Cs-137	B400 Bunker	IPL Model HEG-137 Serial No. MM-311	Source check and calibration for the generator package monitoring system.
600	288 μ Ci Cs-137	10A	IPL Model RV-137-250U Serial No. 644-72-6	Source checks.
600	253 μ Ci Cs-137	3A	IPL Model RV-137-250U Serial No. 686-12-7	Source checks.
600	283 μ Ci Cs-137	6B	IPL Model RV-137-250U Serial No. 644-72-11	Source checks.
600	288 μ Ci Cs-137	3A	IPL Model RV-137-250U Serial No. 644-72-13	Source checks.
600	271 μ Ci Cs-137	3A	IPL Model RV-137-250U Serial No. 644-72-10	Source checks.
600	296 μ Ci Cs-137	7A	IPL Model RV-137-250U Serial No. 644-72-16	Source checks.
600	277 μ Ci Cs-137	7F	IPL Model RV-137-250U Serial No. 644-72-14	Source checks.
600	274 μ Ci Cs-137	1B	IPL Model RV-137-250U Serial No. 644-72-15	Source checks.
600	279 μ Ci Cs-137	6A	IPL Model RV-137-250U Serial No. 644-72-18	Source checks.
600	258 μ Ci Cs-137	1C	IPL Model RV-137-250U Serial No. 1047-69-4	Source checks.
600	246 μ Ci Cs-137	6B	IPL Model RV-137-250U Serial No. 1014-93-3	Source checks.

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600	248 μ Ci Cs-137	1C	IPL Model RV-137-250U Serial No. 1014-93-5	Source checks.
600	250 μ Ci Cs-137	3A	IPL Serial No. 1169-18	Source checks.
700	283 μ Ci Cs-137	711	IPL Model RV-137-250U Serial No. 644-72-17	Source checks.
700	1 Curie Cs-137	711	Amersham Serial No. 4785GG	Source checks.
700	10 millicurie Cs-137	711	3M Model 4F6S Serial No. 68391	Source checks.
800	254 μ Ci Cs-137	803	IPL Model RV-137-250U Serial No. 686-12-18	Source checks.

Proposed Changes to Facilities and Equipment

Proposed changes to facilities and equipment are routed an appropriate change control process prior to receiving approval. These processes include provisions for review of applicable changes by the Radiation Safety Officer or designee.

The RSO or designee performs an evaluation to determine the potential significance of the proposed changes. If the RSO or designee determines the modifications may be significant, he or she submits the change to the RSC for review and approval/denial. A modification will be deemed significant if the modification could result in significantly elevated radiation levels, elevated personnel exposures, elevated airborne concentrations, or elevated radioactive waste production.

Typical laboratory classification criteria outlined by the IAEA and other standard setting organizations are not directly applicable at our facility. Due to the relatively unique operations at our facility, we classify our laboratories as "production" and "other". Production laboratories are, by their nature, good quality chemical laboratories. Due to the scale of our operations, special facilities specifically designed for utilizing radioactive materials are used for radiopharmaceutical production processes. These facilities also incorporate features to ensure we meet FDA current good manufacturing practices (cGMP's).

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Radiation Safety Program

10.1 Audit Program

The audit program at the Maryland Heights site consists of three primary elements. The RSC audits, the Health Physics Area audits, and the Health Physics Process audits. The latter two types of audits may be combined into a single audit.

Radiation Safety Committee Audits

The RSC will direct at least two annual audits. The audits that will be conducted annually include:

- 1) An ALARA Audit to ensure exposures at the plant are maintained as low as reasonably achievable.
- 2) A Radiation Protection Program audit to ensure the site Radiation Protection Program complies with applicable regulations, license commitments and site policies.

Health Physics Area Audits

Health Physics will conduct an Area Audit, at least annually, of all areas where significant work with radioactive materials occurs. These audits will focus on physical observations of the facilities and equipment, as well as the radiation safety practices and knowledge of the individuals working in the area. It will not focus on specific processes or procedures being conducted in the area.

Each area audit will utilize a check sheet designed to ensure specific regulatory requirements, license commitments, and site policies are being met. Examples of the current required observations include:

- 1) Are personal dosimetry devices being worn appropriately?
- 2) Are dosimetry devices being worn in the location of highest exposure?
- 3) Are all entrances to the laboratory properly posted?
- 4) Is installed equipment being utilized to minimize exposure?
- 5) Are containers and samples properly marked to indicate the presence of radioactive materials?
- 6) Are an appropriate number and type of survey meters available for the work being conducted?

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- 7) Is available equipment in working order and in calibration?
- 8) Are required instrument source checks being performed?
- 9) Are personnel in the area wearing the appropriate level of Personal Protective Equipment?
- 10) Are radioactive wastes being segregated according to site policy?
- 11) Do work activities in the lab have the potential to cause dose rates in adjacent areas in excess of 5 mR/hr?

In addition, selected personnel working in the area are interviewed to determine their level of knowledge of specific regulatory and site specific radiation safety requirements. All interviews utilize a defined set of questions as well as any additional questions the auditor feels are appropriate for the area. Examples of the current questions/observations include:

- 1) What are the site ALARA goals for your department?
- 2) What is the site administrative limit for Deep Dose Equivalent and Shallow Dose Equivalent - Maximum Extremity?
- 3) What are your actions in the event of an evacuation alarm?
- 4) What are your actions in the event you discover a fire involving radioactive materials?
- 5) Where do you find the action levels for reporting radiological events?
- 6) How do you report a safety concern?
- 7) When are you required to utilize a portal monitor?
- 8) Request the employee demonstrate proper donning and removal of PPE.
- 9) Request the employee demonstrate proper method for performing surveys required to leave their work area.

Process Audits

Health Physics will audit each radioactive product manufacturing process at least annually. Process audits will include a review of the appropriate procedures and batch sheets. It will also include observation of either selected aspects of the

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process, or the entire process, with particular attention being paid to ALARA techniques, exposure control, contamination control, and effluent minimization.

Audit Response

A written response is required for all three types of audits. Area supervisors are responsible for preparing the response and following up on identified corrective actions. Health Physics will review the most recent audit of the area or process prior to initiating a new audit. This will ensure identified corrective actions are completed.

In addition to these formal audits, representatives of the Health Physics Department visit most areas of the plant while performing routine Health Physics tasks. This allows for rapid identification and correction of poor practices or deviations from approved policies and procedures.

Modifications to the Radiation Safety Audit Program

Proposed modifications to the Audit Program will first be reviewed by the RSO. If the proposed modification is deemed significant, or if the potential exists that the modification would decrease the effectiveness of the radiation safety program, the modification will be referred to the Radiation Safety Committee for their review and approval/denial prior to implementation.

10.2 Radiation Monitoring Instruments

Selection Criteria

Portable Radiation Level Measuring Instruments

Instruments used in determining the exposure rate from a beta-gamma radiation source shall be selected based on matching their energy response, energy range, linearity, exposure rate range, and radiation type to the radiological conditions to be measured. Generally, radiation level surveys will be performed with energy compensated Geiger-Mueller (G-M) detectors such as an Eberline HP-270 or equivalent. Exposure levels above the normal range of these instruments may be assessed using ionization chambers such as the Eberline RO-20 or equivalent or "teletectors" such as the Xetex 330A Telescan or equivalent. Micro-R meters are used in certain low exposure rate conditions. These meters utilize either G-M or scintillation type detectors and are useful for beta-gamma radiation sources.

Portable Contamination Level Measuring Instruments

Instruments used in determining the contamination level from a radioactive source shall be selected based on matching their energy response and range, linearity, count-rate range and radiation type to the radiological conditions to be measured.

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This site generally uses a two tier approach to personal contamination surveys. The first station is normally a pancake type G-M probe connected to a count rate meter. The second station consists of a beta-gamma scintillation detector connected to a count rate meter. Most count rate meters have an upper limit of 500,000 cpm. In the event this limit is exceeded, a radiation level meter would then be used. The overlapping radiation type response provides greater assurance that those nuclides in use at this facility will be detected.

Stationary Counting Equipment

Removable contamination levels are assessed using manual and automatic NaI scintillation detectors. We currently have numerous NaI well detectors located in various laboratories around the site.

Environmental sample counting, as well as general radionuclide identification, is performed on high purity germanium (HPGe) solid state detector systems connected to multichannel analyzers. These gamma spectroscopy systems are capable of covering the photon energy range from 20 to 2000 keV and use computer software algorithms to identify and quantify levels of radioactivity present in a sample.

The thyroid bioassay stations use NaI detectors coupled to multichannel analyzers. The output is fed into a combination of off-the-shelf and custom software for assay of the thyroid burden.

Overview of Radiological Instrument Calibration Program

Portable Radiation and Contamination Level Measuring Instruments

The G-M and ion chamber instruments are calibrated on an annual basis through an in-house calibration program. This program uses two NIST traceable Cs-137 sealed sources that are capable of generating precise exposure rates from 0.1 mR/h to 8 R/h. Instruments with ranges below or above these exposure rates are either sent to an appropriate off-site calibration facility or those ranges are marked as "not calibrated".

Count rate instruments and their associated detectors are calibrated on an annual basis through an in-house calibration program. This program uses NIST traceable sources with a range of beta energies and electronic pulsers. For those contamination survey instruments not used for dose assessments or free release surveys, a single source is used to assess the instruments response to radiation.

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Portal Monitors

We currently utilize eight stationary portal monitors at the Maryland Heights site. We utilize two different models, i.e., NNC Gamma-60 units and Canberra GEM-5 units. The portal monitors are located to ensure individuals leaving restricted areas are not contaminated with radioactive materials.

The site portal monitors are calibrated semi-annually. A “reliably detected activity” check is performed on a monthly basis and a sensitivity test is performed weekly. All calibration and testing is done with a NIST traceable source.

Four of the portal monitors are scheduled to be replaced with new Canberra GEM-5 units (2009). Procedures have been developed for the calibration and source-checking of these units.

Stationary Counting Equipment

The manual and automatic NaI equipment are checked for efficiency using a Cs-137 source. These systems have had isotope specific efficiency factors experimentally determined for standard sample geometries.

An automatic calibration program is run on the liquid scintillation counter (LSC) each day of use. This calibration routine automatically calibrates and adjusts the LSC for optimal performance. The system monitors the background counts, efficiency, and Chi-square values.

The high-purity germanium gamma-ray spectroscopy systems are calibrated on an as needed basis for energy, shape and efficiency. Efficiency calibrations are performed for desired geometries. The calibration sources used are all NIST traceable. Calibration checks are performed on the gamma spectroscopy systems each day of use by measuring multiple system parameters, such as peak centroid, Full Width at Half-Maximum (FWHM) and nuclide activity. Control charts are generated and reviewed for trends.

Thyroid monitoring systems are checked on a daily basis prior to operation. Daily checks are performed on the system by measuring Peak Centroid, FWHM and Activity using NIST traceable sources recommended by the vendor. Additional QA parameters such as Chi-Square calculation and Minimum Detectable Activity are checked on a quarterly basis.

All stationary counting equipment is calibrated and maintained by the Health Physics Department. Sources are provided by outside vendors or by the Maryland Heights Radiation Physics Department.

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Portable Radiological Instrument Calibrations

The Health Physics Department (HPD) is responsible for the portable instrument calibration program. Calibration procedures are reviewed by the Radiation Safety Officer or designee.

Training of the calibration technicians in instrument calibration techniques is accomplished by a combination of orientation and on-the-job training. During training, technicians observe calibrations, and perform calibrations under observation. The calibration technicians also receive training in the principles and practices of radiation protection, radioactivity measurements, monitoring techniques, instrument use, and biological effects of radiation as part of their initial and recurring radiation worker training.

Radiation sources available for radiation level calibration use include 1 Ci and 5 Ci Cs-137 collimated sources manufactured by J.L. Shepherd. The useful calibration range using these sources is 0.1 mR/h to 800 mR/h and 2 R/h to 8 R/h respectively. Instruments with ranges requiring exposure rates greater than 8 R/h are sent to either the original manufacturer or another suitable calibration facility. Calibration sources for calibrating contamination level measuring instruments are listed in Table 5-1. A Ludlum Model 500 pulser, or equivalent, is used for electronic calibrations and checking discriminator and High Voltage settings.

The output of the 1 Ci and 5 Ci sources is determined annually using an electrometer and ion chambers which have been calibrated by an accredited secondary calibration laboratory (provides NIST traceability). The range tables are then recalculated, using the inverse square law, based on the exposure rate output at one meter. The attenuators for the 1 Ci source are also verified annually.

Calibration of Radiation Level Survey Instruments

1. Prepare calibration sheet with date, instrument information, exposure levels to be checked for "as found" condition, calibration points, and acceptable error.
2. Inspect general instrument condition and record. If instrument is inoperable, repair before proceeding. If battery check fails, replace batteries before proceeding. Adjust zero point if required. Check the high voltage and discriminator settings.
3. Using the appropriate source, detector jig, and placement on the calibration range, expose the instrument at the mid-point of each scale. Record the observed readings in the "as found" section of the form.
4. Linear readout instruments, with a single adjustment control for all scales, shall be adjusted either at the manufacturers suggested point or

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at a point within the normal range of use. If the instrument has individual adjustments for each scale, then each scale shall be adjusted. The readings at 20% and 80% of each scale shall be within $\pm 15\%$ and $\pm 10\%$ respectively of the conventionally true values (CTV). If the instrument cannot be adjusted to fall within this acceptance window, than it shall be repaired or replaced.

Logarithmic readout instruments shall be adjusted according to the manufacturer's specification. After adjustment, the instrument's response shall be checked at one point on each decade. The reading should not exceed $\pm 10\%$ of the full decade value from the CTV.

Microprocessor based instruments, whose linear characteristics have been proven and documented, may be calibrated using only a single point on each scale. Instruments with auto-ranging shall have calibration points far enough away from an auto-scaling point to avoid interference with the calibration.

5. Note final readings on the calibration form. Also note any repairs which may have been necessary.
6. Apply a calibration sticker to the instrument. The calibration sticker will include the date of most recent calibration, initials of the person performing the calibration, due date for the next calibration, and the serial number of the instrument.
7. Return the instrument, along with a copy of the calibration certificate, to the owner. File the original certificate in the instrument records.

Calibration of Contamination Level Survey Instruments

1. Prepare calibration sheet with date, instrument information, count-rate levels to be checked for "as found" condition, calibration points, and acceptable error.
2. Inspect general instrument condition and record. If instrument is inoperable, repair before proceeding. If battery check fails, replace batteries before proceeding. Adjust zero point if required. Check the high voltage and discriminator settings.
3. For instruments with individually adjustable scales, use the electronic pulser. Calibrate the count rate meter using 80% of the full scale point and observe and record the 20%. For instruments with only one adjustment for all scales, calibrate at the mid-point of each scale. Record the readings on the calibration form. If the instrument cannot be

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adjusted to within 20% of the CTV, then the instrument shall be repaired or replaced.

4. Reconnect the detector and count rate meter. Using the appropriate source and detector jig, expose the instrument to the source and determine the detector's efficiency. Record the detector efficiency on the calibration form along with the source to detector distance.
5. Note final readings on the calibration form. Calculate the instrument efficiency for each source used. Also note any repairs which may have been necessary.
6. Apply a calibration sticker to the instrument. The calibration sticker will include the date of most recent calibration, initials of the person performing the calibration, due date for the next calibration, the efficiency(ies) of the meter, and the serial number of the instrument.
7. Return the instrument to the owner. File the original calibration certificate in the instrument records.

Source Checks for Contamination Level Survey Instruments

The following source response check applies to instruments that are used for dose assessments or free release surveys:

1. After an instrument is calibrated a daily source response check is performed to verify the instruments response to radiation and confirmation of the efficiency factor will be sufficient. This testing may be done with the instrument in place.
2. Examine the instrument condition. Pay particular attention to battery level and cable condition. Record information on the data sheet.
3. Using the appropriate jig, place the source (matching the label) in position. Record the count rate.
4. Calculate the current efficiency and compare to the labeled efficiency. Record on data sheet. This value must be within $\pm 30\%$ of the labeled efficiency. If not, remove instrument for a full calibration as outlined above.
5. Update the instrument label with the date and initials of the technician performing the check. Maintain the data sheet in the instrument records.

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Note: For those contamination survey instruments not used for dose assessments or free release surveys, the count rate is compared single count rate is used to assess the instruments response to radiation prior to each use.

Calibration Records

Portable Radiological Measuring Instruments

Calibration records are maintained by the HPD on each portable instrument. These records will include the owner, location, manufacturer's serial and model number, Mallinckrodt number, and all data outlined in the calibration procedure. All repairs performed shall also be included.

The calibration record shall include the sources used in the calibration and the orientation of the detector or instrument in the radiation field.

Portal Monitors

Calibration records are maintained by the HPD on each portal monitor. These records will include the location, manufacturer's serial and model number, Mallinckrodt number, and all data outlined in the calibration procedure. All repairs performed shall also be included. The calibration record shall include the sources used in the calibration.

Stationary Counting Equipment

Calibration records are maintained by the HPD on each system. This information includes the date of calibration, calibration standards used, results of the calibration, instrument location, instrument make/model, and instrument serial number. The person performing the calibration shall sign/initial each calibration form as required.

Air Sample Quantity Measurement

Selection Criteria

An appropriate, calibrated, measurement device shall be used to assess the quantity of air sampled for all air samples collected.

Calibration and Records

All airflow meters used to demonstrate compliance with regulatory requirements will be calibrated, at a minimum, every two years. Special calibrations will be performed any time there is reason to believe the operating characteristics of a

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metering device have been changed, or whenever system performance is observed to have changed significantly.

Modifications to the Radiation Monitoring Instrument Program

Proposed modifications to the Radiation Monitoring Instrument Program will first be reviewed by the RSO. If the proposed modification is deemed significant, or if the potential exists that the modification would decrease the effectiveness of the radiation protection program, the modification will be referred to the Radiation Safety Committee for their review and approval/denial prior to implementation.

10.3 Material Receipt and Accountability

Procurement of Radioactive Materials

All orders for radioactive materials (RAM) ordered by this site go through the Purchasing Department. The purchasing department checks the desired isotope, form, and quantity against our license to ensure we are authorized to receive the isotope, form, and quantity in question. The recurring nature of radiopharmaceutical production dictates that most orders are on an automatic ordering cycle. This automatic ordering system provides for a cyclic, but predictable, inventory of radioactive material at our site. Isotopes new to the Maryland Heights site require approval by the HPD prior to placing an order. This system will ensure that new isotopes would not be ordered without going through the license verification process.

Receipt of Radioactive Materials

Couriers delivering radioactive material to the Maryland Heights site are directed to the appropriate delivery location by our site security staff. The couriers are met at the material receipt area by site security or other approved personnel. The HPD is notified of the arrival of the radioactive material. HPD personnel will then perform material receipt activities in accordance with 10 CFR 20.1906 requirements following written procedures.

With the exception of our return generators and limited quantity materials received under our waste return program, the isotope and quantity to be received is entered into the facility inventory database prior to opening the package. This entry alerts the technician if accepting the radioactive material (RAM) would exceed a pre-defined fraction of our possession limits. If acceptance of the RAM would cause the facility to exceed license limits, technicians are directed to notify the RSO.

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Inventory of Radioactive Materials

Radioactive material is entered into the inventory program at various stages of receipt and production, depending on the isotope. For example, radioactive raw material from outside vendors is entered upon material check-in. Cyclotron produced materials that are processed in Cyclotron Operations are entered into the program after chemical separation and receipt of assay results the quality control lab. Once per day, the radioactive material tracking software recalculates the on-hand quantities of radionuclides by taking into account incoming and outgoing shipments, onsite production data and radioactive decay.

Transfer of Radioactive Materials

We have established and will maintain a program to ensure licensed material shall only be transferred in accordance with the provisions of 10 CFR 30.41. A large portion of our radioactive inventory is transferred under Materials License 24-04206-05MD to persons licensed pursuant to 10 CFR 35 or equivalent licenses in agreement states.

Records of RAM Receipt, Transfer, and Disposal

Records shall be maintained as specified in the table below.

Type of Record	Retention Time
Receipt	While in possession and for 5 years following transfer or disposal.
Transfer	For 5 years following transfer.
Disposal	Until NRC termination of license.
Important to Decommissioning	Until site is released for unrestricted use.

Modifications to the Material Receipt and Accountability Program

Proposed modifications to the administrative procedures associated with the material receipt and accountability program will first be reviewed by the RSO. If the proposed modification is deemed significant, or if the potential exists that the modification would decrease the effectiveness of the radiation protection program, the modification will be referred to the Radiation Safety Committee for their review and approval/denial prior to implementation.

10.4 Occupational Dose

The following policy has been adopted to ensure compliance with the occupational dose limits specified in 10 CFR 20.

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At minimum, any individual who enters a posted radiation area, high radiation area, or radioactive materials area will be issued a whole body dosimeter badge. This practice assures compliance with 10 CFR 20.1502 (a). The whole body badges will be processed by a laboratory accredited by the National Voluntary Laboratory Accreditation Program (NVLAP).

Certain individuals are also assigned electronic personal dosimeters (EPDs) to allow a real-time indication of exposure associated with their job functions. These devices are intended to provide information to the user and to supplement the whole body dosimeters described above. They are not intended to serve as the dose of record. They may, however, provide valuable information to assist in making a dose estimate in the event the primary dosimetry device is lost or damaged.

One or more extremity dosimeters are issued to all individuals who directly handle radioactive material and who are likely to exceed 10% of the extremity limit specified in 10 CFR 20.1201(a)(2)(ii). The evaluation of the need for extremity dosimeters is made by a knowledgeable individual from the Health Physics Department.

Evaluation of historical air monitoring and bioassay data indicates that individuals working in our facility are not likely to receive, in one year, an intake in excess of 10 percent of the applicable ALIs found in 10 CFR 20 Appendix B. As a result, Mallinckrodt Inc. is not required to monitor the occupational intake of radioactive material by our employees.

If an evaluation indicates an individual working under this license has received, or is likely to receive, in one year, an intake in excess of 10 percent of the applicable ALIs found in 10 CFR 20 Appendix B, then appropriate monitoring will be performed and compliance with the dose limits will be accomplished by the appropriate method outlined in 10 CFR 20.1202.

Proposed modifications to the personnel dosimetry program will first be reviewed by the RSO. If the proposed modification is deemed significant, or potentially significant, the modification will be referred to the Radiation Safety Committee for their review and approval/denial prior to implementation.

10.5 Public Dose

A monitoring program will be maintained to ensure compliance with 10 CFR 20.1302(b).

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10.6 Safe Use of Radionuclides and Emergency Procedures

General Topics for Safe Use of Radionuclides

- Wear the appropriate level of PPE in accordance with internal procedures for the area being worked in, and for the process being performed. If an employee is not sure of the appropriate level of PPE, he or she should consult with their Supervisor.
- After working in a posted radiation area or a posted radioactive materials area, personnel will conduct primary and/or secondary personal surveys in accordance with internal procedures.
- Prior to leaving any building on the Maryland Heights site, except certain administrative areas, it is necessary to walk through the designated portal monitor. Use of the portal monitors is described in internal procedures.
- Radiological incidents such as uniform and skin contamination exceeding pre-defined thresholds should be immediately reported to Health Physics in accordance with internal procedures.
- No eating, drinking, smoking, or applying of cosmetics is allowed in any area where licensed material is stored or used.
- No food, drink, or personal effects should be stored in areas where radioactive material is stored or used.
- Wear all assigned dosimetry devices at all times while in posted radiation areas or posted radioactive materials areas.
- Leave all assigned dosimetry devices in the assigned low-background storage area when they are not being worn and each time you leave the site.
- Lost or misplaced dosimetry badges should be reported immediately to a member of the Health Physics Department.
- The exposure indicated on assigned direct-reading dosimeters should be observed frequently. If an individual's dosimeter alarms they should leave the area and report the occurrence in accordance with the internal written procedures.
- Radioactive waste should be disposed of in designated receptacles. Waste should be segregated by form and radionuclide as specified in internal procedures.
- Pipetting by mouth is prohibited.

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- Licensed material must be maintained in posted radiation areas or posted radioactive materials areas. Radioactive material outside of posted areas must be maintained under constant surveillance.
- Any operation involving volatile uncontained radioactive material must be performed in a ventilated hood, glovebox, or hot cell.
- Radioactive material should be transported between locations in a manner to minimize contamination and minimize exposure to the transporter. In general, the material should be placed in an uncontaminated shield and then transferred on a cart. Materials should be placed as far away from the transporter as can safely be accomplished.
- Individuals should be aware of the radiation fields in which they are working by periodically measuring the radiation levels with a survey meter.

Emergency Procedures

In the event of a spill of radioactive materials, affected individuals should take the following actions.

- The employee should announce the spill and make other individuals in the area aware of the spill and its location.
- Any liquids shall be covered with absorbent material, if it is readily accessible, to limit the spread of the spill.
- The emergency number 4-7803 should be dialed to notify the Health Physics Department of the spill.
- Employees should evacuate the immediate area of the spill, being careful to minimize the spread of contamination associated with leaving.
- Employees should restrict access to the area to prevent the spread of the contamination.
- If there is no member of the Health Physics Department on site, a Class I radiation worker from the affected department should be contacted.
- Employees should follow the instructions of the responding Class 1 employee and Health Physics Department staff.
- Spill clean-up will be directed by a member of the Health Physics Department and the clean-up will be handled in accordance with internal procedures.

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Radiological Contingency Plan

As previously mentioned, Mallinckrodt has prepared an emergency response plan in accordance with 10 CFR 30.32(i)(3). This plan would be activated for emergencies which exceed pre-defined thresholds.

Modifications to the Safe Use of Radionuclides and Emergency Procedures

Proposed modifications to the Safe Use of Radionuclides and Emergency Procedures will first be reviewed by the RSO. If the proposed modification is deemed significant, or if the potential exists that the modification would decrease the effectiveness of the radiation protection program, the modification will be referred to the Radiation Safety Committee for their review and approval/denial prior to implementation.

10.7 Surveys

Before allowing site personnel to perform surveys, the RSO will ensure that they have sufficient training and experience to perform surveys independently.

Academic training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection.
- Radioactivity measurements, monitoring techniques, and use of instruments.
- Mathematics and calculations basic to measuring radioactivity.
- Biological effects of radiation.

Appropriate on-the-job training will consist of the following:

- Trainee observing the trainer using survey equipment, collecting samples, and analyzing samples.
- Trainee is then observed using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

Facilities and Equipment for Analyzing Survey Samples

Survey samples will be analyzed in a low background area.

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A gamma-counting instrument will be utilized to count samples containing gamma-emitters and high energy beta emitters (i.e. P-32). Calibrations indicate our gamma counting equipment for wipes have efficiencies of 10-20% for P-32.

A liquid scintillation counter will be used to count samples containing low energy beta emitters.

Ambient Radiation Level Surveys

Dose rate surveys will be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits.

Dose rate surveys will be conducted to ensure the total effective dose equivalent to an individual member of the public does not exceed the limits specified in 10 CFR 20.1301.

Contamination Surveys

Contamination surveys will be conducted:

- To evaluate radioactive contamination that could be present on surfaces.
- After spills and significant contamination events.
- As required by the RSC when radioactive material handling procedures and processes change.
- To evaluate contamination of users, at minimum, at the end of each work day when licensed materials are in use. In practice, users generally perform multiple surveys daily.
- In unrestricted areas adjacent to restricted areas to ensure contamination is not being spread into unrestricted areas.
- In areas through which licensed materials are transferred and stored prior to shipment.

Contamination Survey Frequency

Contamination surveys will be conducted in manufacturing laboratories at least daily on days radioactive materials are used to manufacture radiopharmaceuticals in that laboratory.

Contamination surveys will be conducted in other restricted areas where $> 200 \mu\text{Ci}$ of unsealed radioactive material is used at any one time at least weekly.

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Contamination surveys will be conducted in other restricted areas where $< 200 \mu\text{Ci}$ of unsealed radioactive material is used at any one time at least monthly.

Contamination in Unrestricted Areas

Contamination identified in unrestricted areas will be immediately decontaminated to background levels. If it is not possible to achieve background levels, the area will be reclassified and posted as a restricted area.

Survey Records

Each survey record will include:

- A diagram or description of the area surveyed.
- Specific locations where wipe tests or radiation level readings were taken.
- Contamination or radiation levels with appropriate units.
- Name of the person who conducted the survey.

Air Monitoring in the Workplace

An air monitoring program has been established sufficient to demonstrate compliance with 10 CFR 20.

Airborne Effluent Release Monitoring

When practicable, airborne radioactive effluents are released from monitored release points (i.e. monitored stacks and vents). Effluent monitoring systems are calibrated at least annually.

If necessary, unmonitored effluents will be estimated. Unmonitored releases will not exceed 30% of the total estimated effluent releases or 10% of the permissible air effluent concentrations found in Table 2 of 10 CFR Part 20, Appendix B, whichever is greater.

Liquid Effluent Release Monitoring

Liquid effluents are evaluated to ensure concentrations of radioactive material in water that is released to the sanitary sewer meet the limits specified in 10 CFR 20.2003.

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Bioassay Monitoring

Air sampling and an extensive bioassay analysis database indicates that employees at the Mallinckrodt Maryland Heights Facility are not likely to have internal intakes which exceed the limits specified in 10 CFR 20.1502 (b). As a result, a bioassay program is not required for activities conducted under this license.

If subsequent evaluations indicate intakes are likely which would exceed the applicable limits in 10 CFR 20.1502 (b), a bioassay/air monitoring program will be established to demonstrate compliance with the applicable dose limits.

Special bioassays will be conducted in the event conditions indicate one is warranted. Examples of these types of conditions would include:

- The presence of unusually high levels of facial and/or nasal contamination.
- Entry into posted airborne radioactivity areas without appropriate exposure controls.
- Operational events with a reasonable likelihood that a worker was exposed to significant quantities of airborne radioactive materials.
- Known or suspected incidents of a worker ingesting radioactive material.
- Evidence of failure of a respiratory protection device.

Sealed Source Leak Tests

Leak tests will be conducted on sealed sources at the frequency specified in the respective SSD Registration certificate.

- For each source tested, identifying information such as manufacturer, model number, serial number, radionuclide, activity, and calibration date will be recorded.
- A survey meter will be utilized to measure external dose rates.
- A separate wipe paper will be used for each source.
- The area where contamination would be likely to accumulate (but not necessarily the surface of the source) will be wiped.
- The instrumentation utilized to analyze the wipe sample will be calibrated and will be sensitive enough to detect 0.005 microcuries of the radionuclide.

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- The background for the instrument will be determined.
- The wipe will be counted.
- If the wipe test indicates isotope specific activity on the wipe sample greater than 0.005 microcuries, the source will be removed from service, the RSO will be notified, an appropriate investigation will be conducted, and if subsequent measurement confirms the source is leaking, the NRC will be notified.

Modifications to this Survey and Leak Test Program

Proposed modifications to this survey and leak test program will first be reviewed by the RSO. If the proposed modification is deemed significant, or if the potential exists that the modification would decrease the effectiveness of the radiation protection program, the modification will be referred to the Radiation Safety Committee for their review and approval/denial prior to implementation.

10.8 Transportation

We will maintain a program for the transportation of radioactive materials to ensure compliance with NRC and U.S. Department of Transportation regulations.

10.9 Corrective Action Program

We will maintain a corrective action program to identify and correct deficiencies with Radiation Safety. This program will include provisions for: (1) worker identification of radiation safety issues; (2) prompt notification of management of significant issues; (3) root cause analysis, including associated training for all managers, supervisors, and radiation protection staff involved in performing and reviewing root cause evaluations; and (4) tracking of identified deficiencies.

Section 11

Waste Management

The Mallinckrodt Maryland Heights Facility has a comprehensive radioactive waste management program. This program incorporates both reactor produced waste materials as well as accelerator produced radioactive waste materials. We utilize a number of methods for disposal of radioactive wastes. This includes disposal by transfer to an authorized recipient, decay-in-storage, release into sanitary sewage, and release in airborne effluents. Byproduct wastes will only be disposed of in accordance with one of the methods identified in Subpart K to 10 CFR 20.

We have developed and implemented written waste disposal procedures for radioactive material that meet the requirements of the applicable section of Subpart K to 10 CFR 20. In addition, we have developed and implemented written procedures for customer return of Mallinckrodt supplied safes, vials, packagings, and the remaining radioactive contents to our license. In addition, as per the Mallinckrodt letter to NRC dated December 8, 2005, the site may accept non Mallinckrodt produced Mo/Tc generators and small quantities of waste materials Eu-154, Ba-133, C-137 and/or Co-57 from Mallinckrodt pharmacies. Instructions are provided to our customers and Mallinckrodt pharmacies informing them of the necessary packaging requirements for return to the Maryland Heights site.

ORIGIN ID: ZSVA (800)525-3689
SHIPPING DEPT.
MALLINCKRODT MEDICAL INC.
2703 WAGNER PLACE
MARYLAND HEIGHTS, MO 63043
UNITED STATES US

SHIP DATE: 24AUG09
ACTWGT: 1.5 LB
CAD: 0052080/CAFE2431

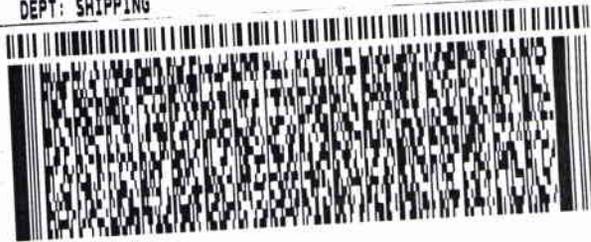
BILL SENDER

TO ATTN: MR. KEVIN NULL
US NRC REGION III
2443 WARRENVILLE RD. STE 210

LISLE IL 605324523

REF: 020612

DEPT: SHIPPING



FedEx
Express



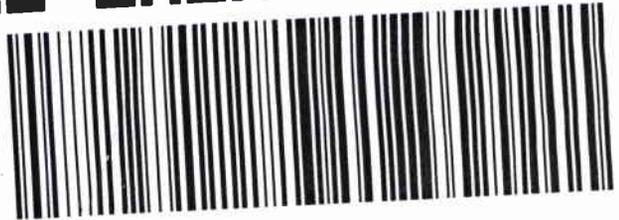
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TUE - 25AUG A1
PRIORITY OVERNIGHT

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